

 Tissue-Tek® AutoTEC®
SAKURA
Automated Tissue Embedding Console

**Operating
Manual**

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Manufactured by:
Sakura Finetek USA, Inc.,
Torrance, CA 90501 U.S.A.

Made in U.S.A.

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TABLE OF CONTENTS

<i>Section</i>		<i>Page</i>
1	INTRODUCTION	
	Safety Precautions	1.1
	General Description	1.1
	Location of Major Systems and Components	1.1
	Specifications	1.6
	Safety Standards	1.7
2	INSTALLATION	
	General Information	2.1
	Environmental Factors.....	2.1
	Unpacking and Installation	2.1
	Moving.....	2.2
3	CUSTOMIZATION OF SETTINGS	
	General Information	3.1
	Map of Interface Screens.....	3.5
	Access Levels	3.6
	Configuring System Settings	3.7
4	OPERATION	
	Initial Start-up.....	4.1
	Typical Operating Sequence.....	4.1
	Routine Operation	4.2
5	CARE OF THE INSTRUMENT	
	Introduction	5.1
	Routine Maintenance	5.1
	Paraffin Reservoir and Filter Cleaning	5.2
	Magazine Cleaning.....	5.4
	Output Door Inspections and Cleaning	5.4
	Splash Guard Cleaning.....	5.4
	Optional: Touch Screen, External Keyboard, and Mouse Cleaning	5.4
	Gripper Weekly Maintenance.....	5.5

TABLE OF CONTENTS

<i>Section</i>	<i>Page</i>
6	TROUBLESHOOTING
	Error Recovery 6.1
	Error Codes and Messages 6.2
	Error Recovery Procedure 6.7
7	SERVICE AND REPLACEMENT PARTS
	Service 7.1
	Replacement Parts 7.1
	APPENDIX A
	Glossary A.1
	APPENDIX B
	Index B.1
	APPENDIX C
	Grossing Procedures for Paraform® Sectionable Cassettes C.1
	APPENDIX D
	Microtomy Procedure for Paraform® Sectionable Cassettes D.1

INTRODUCTION

Safety Precautions

WARNINGS, CAUTIONS, and NOTES are provided throughout this manual to indicate levels of potential hazards as defined below:

WARNING: Identifies a potential hazard where failure to follow instructions may result in serious injury or death to the operator and/or other personnel.

CAUTION: Indicates a potential hazard where failure to follow instruction may result in damage to the Tissue-Tek® AutoTEC® and/or other property.

NOTE: Indicates a reminder or other helpful information.

General Description

The Tissue-Tek® AutoTEC® is a reliable, high-quality, precision instrument that fully automates the embedding process using the innovative Tissue-Tek Paraform® Sectionable Cassette System. The Tissue-Tek AutoTEC embeds diagnostic, human, and research tissue specimens continuously enabling laboratories to:

- Significantly improve throughput time
- Enhance procedure standardization and specimen consistency
- Reduce repetitive movement disorders and exposure to harmful chemicals
- Offer a continuous method of tissue specimen embedding that eliminates the need to handle samples in batches
- Automatically embed up to 120 specimens per hour, which improves productivity
- Enhance efficiency, consistency, and standardization of laboratory procedures and operations
- Provide robotic precision and consistency, minimize the bottom paraffin layer, and eliminate excess paraffin around the cassette border
- Reduce labor requirements

Tissue-Tek Paraform Cassettes are made of two components, an inner sectionable tissue insert and an outer frame that provides support when in the microtome chuck. Paraform Cassettes are placed in up to four 32- or 20-cassette input magazines. The magazines are loaded with the cassette front surface angled facing up during the embedding process.

Following a magazine warm up period of 15 minutes, the instrument's robotic system:

- Sequentially removes each cassette from the magazines
- Identifies the type of cassette (standard, biopsy, orientation, core biopsy, shaved biopsy, or 13 x 13)
- Places the cassette in the properly sized pre-heated base mold
- Pushes down (stages) the cassette until it reaches the bottom of the base mold
- Dispenses a precise amount of paraffin to match the tissue size while holding the cassette in place

The base mold cools to form a solid paraffin block. The robotic system removes the paraffin block from the mold and presents it to sensors that verify that a frame is present and correctly positioned in the robotic gripper, and that a paraffin block is in the frame. The robotic system places the paraffin block in one of the four 32-position output doors.

Each output door can be detached from the instrument and used as a transport tray to a microtome workstation. Springs hold the paraffin blocks securely in place while enabling them to be easily removed.

Location of Major Systems and Components

The Tissue-Tek AutoTEC instrument is comprised of the following major systems and components (Figures 1-A through 1-C). A detailed description is given in the following paragraphs.

INTRODUCTION



Figure 1-A: Front View and Left Panel

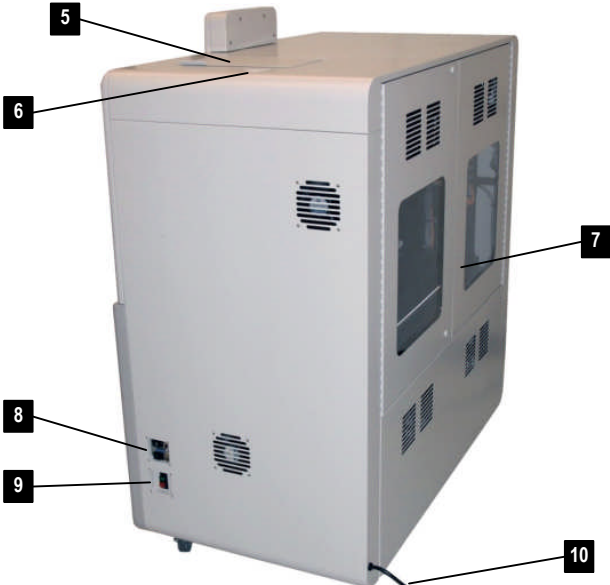


Figure 1-B: Rear View and Right Panel

Location	Component
1	Touch screen monitor
2	Main door, for access to input door, output doors and paraffin drip tray
3	Front door, equipped with safety interlocks. Allowing operator easy access to base molds and air filter
4	Paraform recovery chute door, for retrieval of rejected cassettes
5	Paraffin reservoir lid; opens to allow addition of paraffin to the system
6	Paraffin reservoir filter access
7	Rear doors, equipped with safety interlocks; give access to robotic system
8	External computer system connections for: • PS2 external pointing device, such as a mouse • PS2 keyboard, to supplement on-screen keypads • RJ-45 Port • USB 2.0 peripherals, including USB 'key' drives used to export log files and other data
9	Main power switch
10	Power cord
11	Input Door, for access to the magazine loading area
12	Disposable Paraffin Trough
13	Four removable output doors, each holding up to 32 blocks

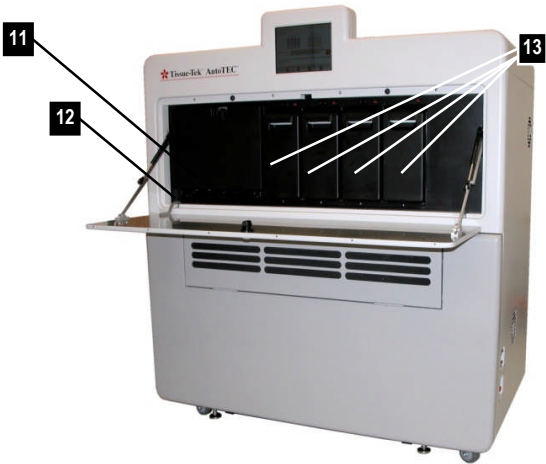


Figure 1-C: Main Door Opened

Input Door and Loading Area (Figure 1-D)

Figure 1-D: Input Door

The input door is accessed by opening the main door (see Figures 1-A and 1-C). The input door is interlocked enabling the operator to insert and remove magazines only when the robotic system is not interacting with the door. An insulated housing enclosure ensures efficient magazine heating. Precise positioning of each cassette ensures accurate placement in the base mold.

The input door includes four individually-controlled heater assemblies (see Figure 1-D, location **14**) that:

- Accommodate one magazine each
- Heat magazines in 15 minutes to prepare cassettes for embedding
- Present Paraform Cassettes consecutively to the gripper

NOTE: The input door cannot be opened during operation unless an on-screen prompt indicates otherwise.

Access to the robotic system is through the two rear doors (see Figure 1-B, location **7**).

NOTE: Before opening the rear doors or the front door, the “Instrument Access” button on the monitor screen must be pressed first. Wait for the AutoTEC to stop the current embedding cycle and to display an acknowledgement prompt on the LCD screen, before opening the doors. Opening the door without waiting for the prompt, can cause robotic system stalls and will delay the normal embedding cycles.



Robotic System (Figure 1-E through 1-H))

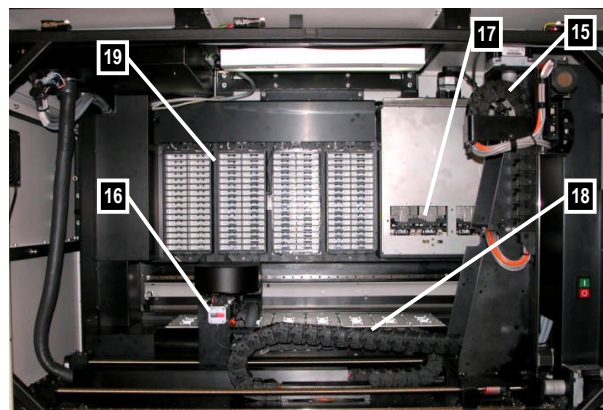


Figure 1-E: Interior View of Robotic System

As shown in Figure 1-E, the robotic system comprises two main modules, a gripper **15**, and a stager **16**, each with three axes of motion. These two modules handle the Paraform Cassettes from the magazine area **17** to the base mold module **18**, and finally to the output door area **19**.

The gripper retrieves Paraform Cassettes from the magazines and moves them through the system. Figure 1-F shows the cassette sensor **20** wide beam sensor **25** and, beneath it, the Paraform recovery chute **21** with chute sensor **26**. The sensors detect an open lid, presence and type of cassette; they also allow the system to determine if the frame is correctly held by the gripper. If a tissue cassette is not present, improperly assembled, or if the frame is incorrectly held, the gripper drops the item into the Paraform recovery chute. If the chute sensor detects an item is dropped into the chute, the system indicates that a cassette was dropped in the chute and the ‘CASSETTES SENT TO CHUTE’ count will be incremented on display.

The gripper is programmed to attempt to pick a framed cassette from a magazine in three attempts.

After the third attempt to pick up a cassette, if the gripper still does not grab a frame from the magazine, the instrument will retry for 3 more times, after cycling the ID motor up and down to sort out the stacks of frames inside the magazines. If after all retries, the gripper still cannot grab a frame from the magazine, the system will alert the operator and wait for the operator to resolve the cassette problem. If the operator does not respond in 30 seconds, the AutoTEC will skip the trouble magazine and start to process the next available magazine.

INTRODUCTION

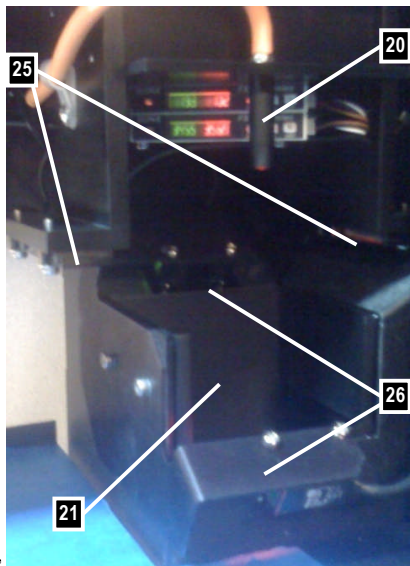


Figure 1-F: Cassette Sensors, Paraform Recovery Chute, Chute Count Sensor, and Wide Beam Sensor

Once a Paraform Cassette has been picked and validated, by the sensors, a small heating unit is engaged to keep the cassette warm during transportation to the base mold. The gripper will then move the cassette to the base mold module (Figure 1-G).

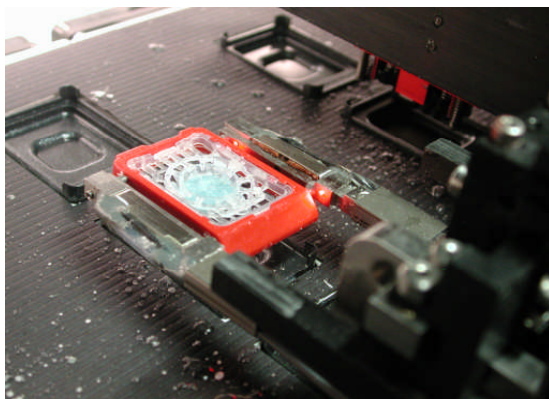


Figure 1-G: The Gripper places a 13x13 Paraform Cassette in a Base mold

The Teflon coated base mold module comprises three channels of eight base molds each. The base molds in the first channel, closest to the back of the system, are sized to accept the larger standard Paraform Cassettes. The base molds in the second channel accept the 26x19mm biopsy and other specialty Paraform Cassettes. The third channel accepts the 13x13mm Biopsy Cassettes. Each

individual base mold is a **Thermo Electric Cooler (TEC)** acting as a heating and cooling element.

The stager (and its paraffin dispensing mechanism) performs the embedding of the Paraform Cassettes as follows.

First, the stager assembly positions the paraffin dispensing mechanism (heated solenoid valve and nozzle) over the cassette already placed into the heated base mold. It then stages (presses down with a tamper) the Sectionable Cassette to lower it through the frame until the cassette bottom is pressed against the base mold surface. The stager dispenses an even flow of molten paraffin to the correct volume. Since the temperature and flow are controlled, bubble production is minimized; however, tiny to small bubbles in the formed block are not unusual. Figure 1-H shows paraffin being dispensed into a base mold.

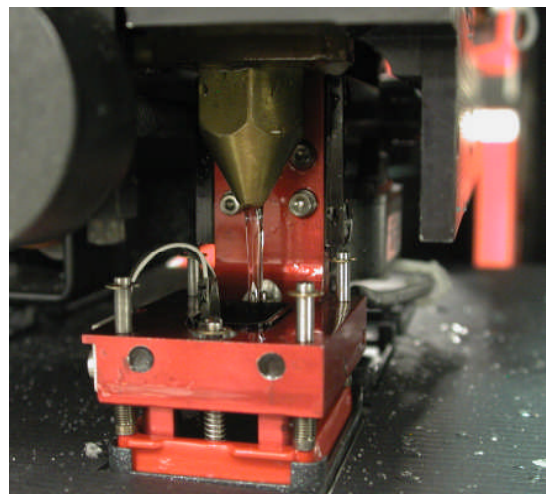


Figure 1-H: Stager Dispensing Paraffin

Two paraffin dispensing methods are available, Standard or Pre-fill, configurable in Service Mode. Standard method dispenses a fixed amount of paraffin in a single shot. Pre-fill method dispenses the fixed amount of paraffin in two separate shots, the first shot is dispensed into the base mold before the cassette is placed and the second shot is dispensed after the cassette is staged. Please contact Sakura, if the Pre-fill method is needed.

When paraffin is dispensed, the base mold switches to its cooling mode. Once the block has solidified, the stager moves away and the gripper comes back to demold the block and to place it in one of the empty positions of the output doors.

Output Doors (Figure 1-I)

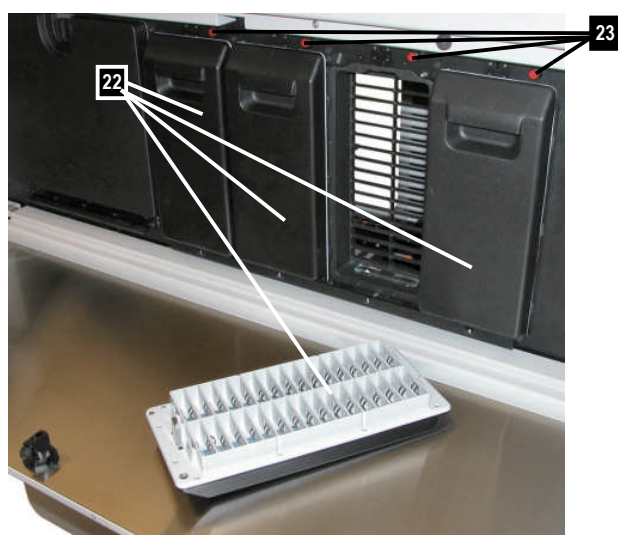


Figure 1-I: Output Doors

The four output doors **22** are interlocked to prevent operator access while the robotic system is interacting with the doors. Each of the four output doors includes a spring-loaded matrix that holds embedded blocks firmly in place, yet enables them to be removed easily. Each door accepts up to 32 Paraform blocks. When the touch screen monitor displays that access is granted, the door can be removed by pressing the associated red interlock button **23**. The removed output door can be used as a secure tray to transport embedded cassettes to the next phase of the histological process. Extra output doors are provided so that the continuous flow is not interrupted waiting for the output door to be returned.

Paraffin Reservoir (Figure 1-J)

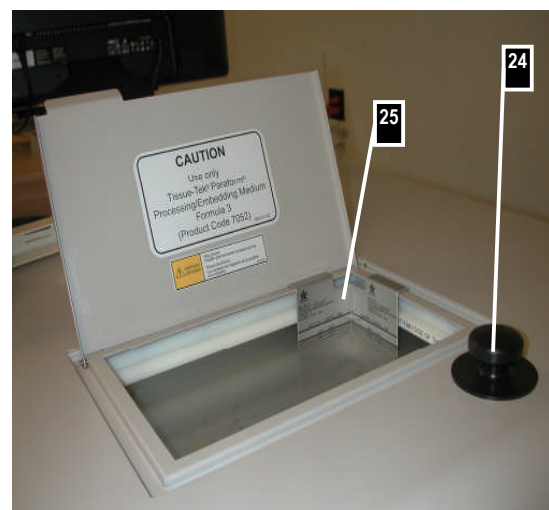


Figure 1-J: Paraffin Reservoir, Lid Open

The paraffin reservoir stores and heats up to 5.38 liters of paraffin. This is enough to embed up to 960 Paraform cassettes, or approximately eight hours of operation.

For superior results and to minimize the production of bubbles, only use the Tissue-Tek Paraform Processing/Embedding Medium, Formula 3 (product code 7052).

The paraffin reservoir includes an ultrasonic sensor to detect the paraffin level in the reservoir and a filter assembly that prevents foreign particles from entering the paraffin delivery tube. The filter can be accessed by removing the black cap **24**. A clip-on paraffin fill gauge is located at the corner of the reservoir to indicate the number of paraffin bags that can be added to fill the reservoir full without overfilling **25**. This clip can be relocated to any corner of the reservoir for better viewing.

INTRODUCTION

Control Panel (Figure 1-K)

The Tissue-Tek AutoTEC operator interface is a touch screen control panel that operates a Windows®-based application program.

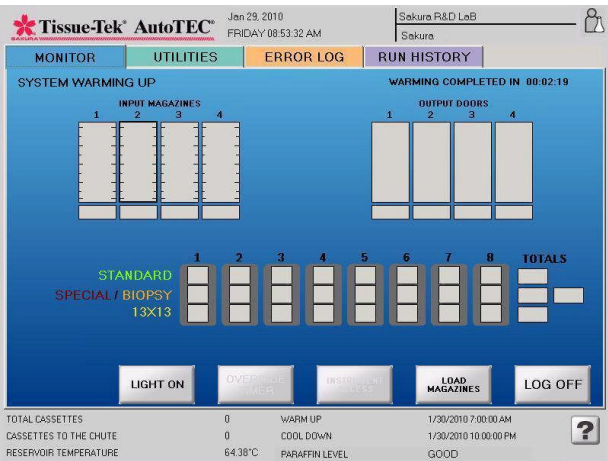


Figure 1-K: The AutoTEC touch screen operator interface

The touch screen diagonal size is 26.7 cm (10.5 in.).

Custom application software includes the following modules:

- Instrument set-up
- Startup and Self checking
- Password and security handling
- Run history
- Graphical depiction of magazine and output door activities
- Statistics setup and recording
- Error logging, error checking and recovery
- Automated warm up and cool-down timing
- Service, maintenance, and troubleshooting interfaces

Specifications

Models Covered by this Manual

Model	Name/Description
7000	Tissue-Tek® AutoTEC® Automated Tissue Embedding Console (115 VAC) (USA)
7001	Tissue-Tek® AutoTEC® Automated Tissue Embedding Console (100 VAC) (Asia)
7002	Tissue-Tek® AutoTEC® Automated Tissue Embedding Console (230 VAC) (Europe)

Power Ratings and Requirements

Model	Power	Frequency	Facility Requirement
7000	115 VAC $\pm$ 10% @ <15A	60 Hz	20A
7001	100 VAC + 10%/–5% @ <15A	50/60 Hz	20A
7002	230 VAC $\pm$ 10% @ < 7A	50 Hz	10A

We recommend an uninterruptible power supply (#7011 or #7146) or at least a dedicated line with an appropriately rated line conditioner.

Noise Level

Less than 65 db

Environmental Requirements Operating:

Temperature Range: +15°C to +35°C

WARNING: IF TEMPERATURE REACHES +36°C OR HIGHER EMBEDDING WILL STOP, UNTIL AMBIENT TEMPERATURE IS LOWERED.

Nominal Temperature: +22°C $\pm$ 2°C

Relative Humidity: 20% to 85%, non-condensing

Nominal Humidity: 40% $\pm$ 20%

Relative Atmospheric Pressure: 70 to 106 kPa

Storage:

Temperature Range: -10°C to +65°C

Relative Humidity: 20% to 95%, non-condensing

Relative Atmospheric Pressure: 70 to 106 kPa

Dimensions and Weight

Height:	154 cm (60.6 in.)
Width:	136 cm (53.7 in.)
Depth:	76 cm (29.9 in.)
Weight:	386 kg (850 lbs)

Instrument Life Expectancy

7 years, based on eight hours of operation, five days a week, with a maximum of 960 cassettes per day; if the operating and instrument care instructions found in this manual are followed, and if preventative maintenance is performed at least once every year by a qualified service technician.

Safety Standards

Electrical Safety

The Tissue-Tek® AutoTEC® has been tested and it complies with the following standards:

- UL 61010A-1
- UL 61010A-2-010
- CSA-C22.2 1010.1-92
- CSA-C22.2 1010.2.010 R(1999)
- IEC 61010-1
- IEC 61010-2-010
- EMC EN 61326=1998
- CE compliance to directive 98/79/EC

Regulatory Information

FDA registered with ETL evaluation (USA); complies with requirements of The Pharmaceutical Affairs Law (Japan); CE registered in compliance with the requirements of EMC Directive, LV Directive in Europe (Europe), In Vitro Diagnostic Device Directive

California Building Code

Fixed Equipment Anchorage Pre-Approval

- CBC-2001: OPA-1866
- CBC-2007: OPA-1866-07

INTRODUCTION

INSTALLATION

General Information

This section provides information on determining a location for and installing the Tissue-Tek® AutoTEC®. The Tissue-Tek AutoTEC must be located and installed correctly to ensure proper operation and service.

Read this operating manual carefully before attempting to operate the Tissue-Tek AutoTEC instrument. Follow all instructions carefully.

CAUTION: The Tissue-Tek AutoTEC should be installed, adjusted, and serviced by a qualified service technician only.

CAUTION: The Tissue-Tek AutoTEC is a precision instrument and must be handled accordingly. Rough handling will disturb or damage internal components. Always handle the instrument with care.

WARNING: DO NOT PLUG IN THE AUTOTEC POWER CORD. AN AUTHORIZED SERVICE TECHNICIAN MUST FIRST VERIFY THE POWER LINE MEETS SPECIFICATIONS.

Environmental Factors

The Tissue-Tek AutoTEC should be located in a temperate and humidity-stable environment avoiding prolonged exposure to excessive temperature and humidity. Temperature and humidity should be held relatively constant to obtain the highest degree of operating stability. Nominal ambient operating temperature conditions are $22^{\circ}\text{C} \pm 2^{\circ}$ ($71.6^{\circ}\text{F} \pm 3.6^{\circ}$). Nominal operating humidity conditions are $40\% \pm 20\%$ relative humidity.

Locate the instrument in a well-ventilated area, avoiding exposure to corrosive vapors, direct air currents, or temperature extremes. Avoid exposure to direct sunlight, open windows, sinks, ovens, open flames, hot plates, radiators, and dry ice baths. Install the instrument on a solid level floor surface away from any equipment that consumes a high voltage or large current, including large refrigerators and ovens.

For proper operation, maintain a six-inch (15.24 cm) minimum clearance around the sides and back of the instrument. For additional stability, lower the feet located on the bottom of the instrument. To lower the feet, turn the nut fastened to the threaded shaft of each foot clockwise

until the foot contacts the ground, but without lifting the caster off the ground.

Unpacking and Installation

The Tissue-Tek AutoTEC is shipped in a large carton. Inspect the carton for shipping damage. If there is visible shipping damage, immediately file a complaint with the carrier and notify Sakura Finetek or the distributor.

Standard Accessories Kit

The following additional items are shipped with the Tissue-Tek AutoTEC:

- Two spare output doors (in addition to four installed on the AutoTEC)
- Paraffin Scraper
- Door opening tool
- Operating Manual (this document)
- Quick Reference Guide
- One case (8 x 1kg) of Tissue-Tek Paraform Processing/Embedding Medium, Formula 3, product code 7052

Shipped separately:

- One package of paper disposable paraffin troughs (12/cs), product code 7010
 - One of the following options:
 - Six 32-position magazine assemblies if a Tissue-Tek® VIP® Tissue Processor is in use in the Laboratory.
- OR
- Six 20-position magazine assemblies and six handles if a Tissue-Tek® x Series® Rapid Tissue Processor is in use in the Laboratory

Missing or Damaged Items

Verify that each item listed on the packing list is included in the carton. Ensure that all packaging materials have been removed and carefully checked for all parts.

If any items are visibly damaged, or are missing, call 1-800-725-8723 or 1-310-972-7800 (U.S. Customers only). If located outside the U.S., contact the nearest Sakura Finetek instrument distributor.

INSTALLATION

Moving

If it is necessary to move the AutoTEC to a new location, allow the paraffin to cool enough to solidify before any movement occurs. Once the main power switch has been turned off, open the reservoir access door to let heat out to speed the paraffin cooling process.

CAUTION: Do not move the Tissue-Tek AutoTEC while paraffin is in a liquid form in the reservoir.

To move the AutoTEC:

1. Select the UTILITIES Tab (Figure 2-A). Press the SHUT DOWN button and wait for the AutoTEC software and Windows operating system PC to shut down completely.

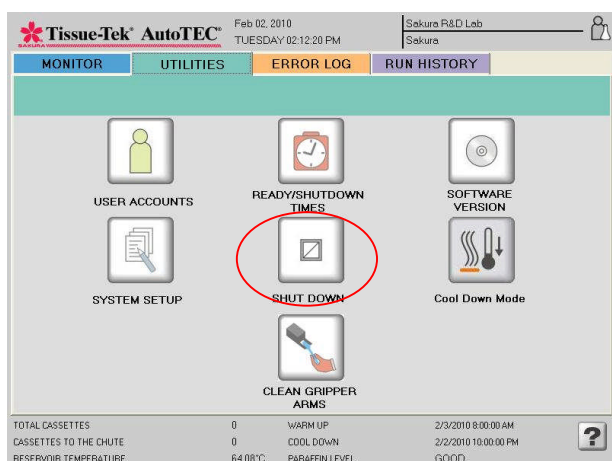


Figure 2-A: Utilities Tab

2. Turn off the main power switch which is located on the right-side panel in the lower-left corner. (See Figure 2-B.)



Figure 2-B: Main Power Switch

3. Disconnect the power cord from the outlet.
4. Raise the feet located on the bottom of the instrument by turning the nut fastened to the threaded shaft of each foot counter-clockwise.
5. Carefully roll the instrument on its casters to the desired location.
6. If desired, lower the feet by turning the nut fastened to the threaded shaft of each foot clockwise.

CAUTION: At least two people should move the Tissue-Tek AutoTEC. Although the instrument is on casters, it is large and heavy and contains sensitive electronic components.

CAUTION: When moving the Tissue-Tek AutoTEC, do not grasp or lift the instrument by its front panel or the side panels.

CAUTION: Ensure that the feet are lowered to hold the instrument securely in place for stationary use.

CAUTION: If AutoTEC is anchored to the building structure per California Building Code, remove the securing hardware first, before moving the AutoTEC.

CUSTOMIZATION OF SETTINGS

General Information

The four Tissue-Tek® AutoTEC® main tabbed screens (MONITOR, UTILITIES, ERROR LOG, and RUN HISTORY) are shown in the following figures.

Before a user logs in, only the MONITOR screen is available for viewing the status of the instrument with all buttons disabled (grayed out) and tabs not functioning (Figure 3-A).

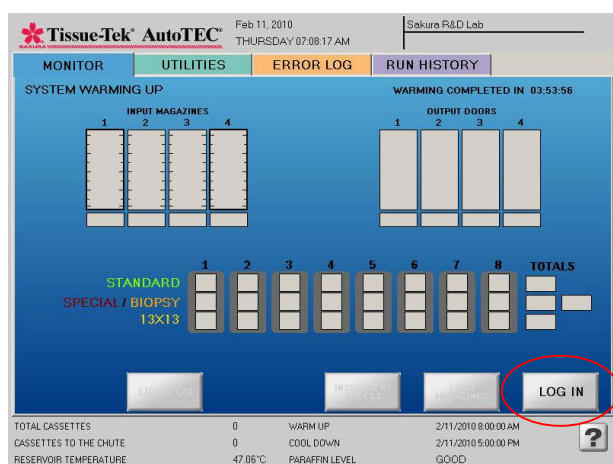


Figure 3-A

To log in to the AutoTEC, press the **LOG IN** button on the MONITOR screen to access the Enter Password keypad. Type in the password followed by pressing the **ENTER** button to log in (Figure 3-B).

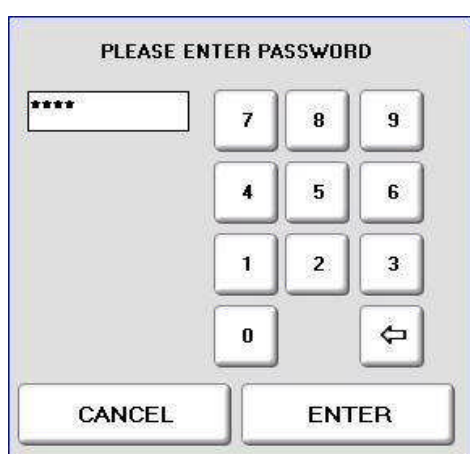


Figure 3-B

After a successful log in, display screens can be changed by selecting the tab for each screen and buttons are enabled to allow the initiation of the embedding process.

MONITOR Screen

Monitor screen is displayed when the MONITOR tab is selected (Figure 3-C).

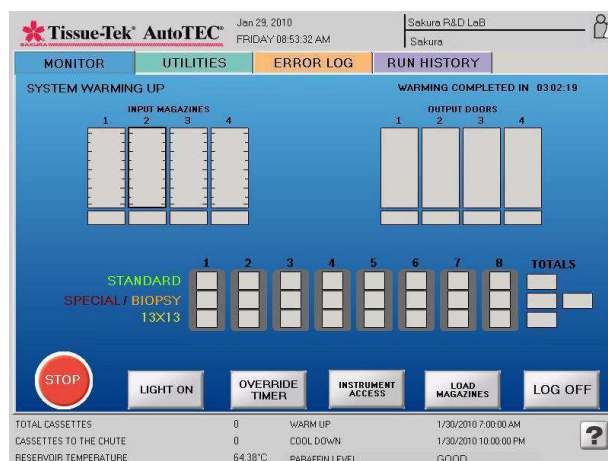


Figure 3-C

- Time and date are displayed at the top center of the screen.
- Institution name and the current logged in user name are displayed at the top right corner of the screen.
- Tabs to allow screen changes between MONITOR, UTILITIES, ERROR LOG, and RUN HISTORY. (There is a SERVICE mode which is only shown with Service level log in).
- Graphical representation of Input Doors and Output Doors area. There are individual counters for the number of cassettes in the Input Doors and the number of embedded blocks in the Output Doors.
- Graphical representation of the Base Mold area with individual counters for each of the 6 cassette types. (Standard, Biopsy, Orientation, Core Biopsy, Shaved Biopsy, and 13x13).

CUSTOMIZATION OF SETTINGS

Button Descriptions



STOP

When selected, it pauses the current instrument activities and displays a dialog box that enables the operator to either resume the activity or abort it. To abort, the person currently logged in, must log in again. The system would then transfer all cassettes present in the base molds to one of the output doors and will ask the operator to remove the magazines from the loading area. Operation will then stop. If the current login password is not entered, or if no selection is made within 30 seconds, operation will resume automatically.

NOTE: The STOP button only appears while the system is embedding.



LOG IN

OR



LOG OFF toggle

This is used to allow a user to Log in or Log off the system.



LIGHT ON/LIGHT OFF toggle

This is used to turn the internal chamber light ON or OFF. If left on, the light will automatically turn off after 30 minutes of inactivity.



OVERRIDE TIMER

When displayed, it allows the user to override the four hour warm up timer. This button appears only if paraffin temperature has reached the factory set temperature. If cassettes are present and the magazines have been warmed for 15 minutes, the system will start embedding when this button is pressed.



INSTRUMENT ACCESS

When displayed, it allows the user to pause the system operation, access the interior of the system by opening the front or rear doors, and resume operation by touching OK in an on-screen prompt.



LOAD MAGAZINE

When displayed, it allows the user to request access to the input door. Once the instrument has initialized the door mechanism, the ID interlock is released and magazines can be removed and inserted. Inserted magazines will be subject to a 15 minute warm up period before embedding starts.

NOTE: If previously inserted magazines have already been warmed for 15 minutes, embedding will automatically start or resume for these magazines as soon as the door is closed and locked.

At the bottom of every screen:

- Total number of cassettes embedded, the number of cassettes thrown to the chute and the reservoir paraffin temperature are displayed at the lower left corner of the screen.
- The next programmed warm up time, cool down time, and the current reservoir paraffin fill level status are displayed at the lower right corner of the screen.
- The indicated Paraffin levels are:
 - Good
 - Low (xxx), the "xxx" number inside the parenthesis is the numbers of cassettes that can be embedded with the amount of paraffin left inside the reservoir. When paraffin level is first detected Low, 128 cassettes can still be embedded without any refill. This number counts down from 128 to 0.



HELP

- When selected, pops up context sensitive help menu.

UTILITIES Screen

Utility screen is displayed, when the UTILITIES tab is selected (Figure 3-D).

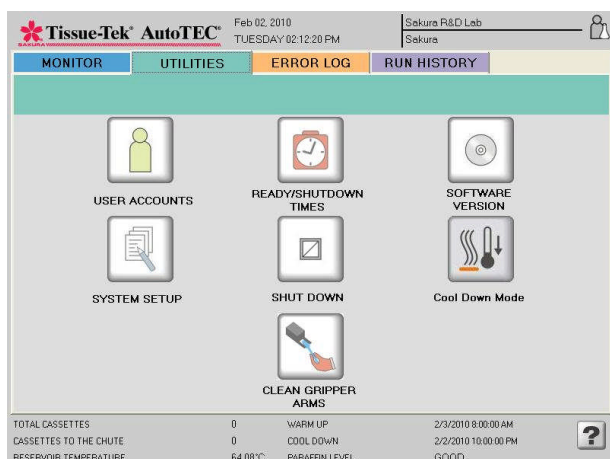


Figure 3-D

Button Descriptions



USER ACCOUNTS

When selected, is used to manage user accounts, such as Add, Edit, and Delete users.



READY/ COOL DOWN TIMES

When selected, is used to set up automatic system ready and cool down times for each day of the week or to control this ready/cool down time manually. This is also used to select off days.



SOFTWARE VERSION

When selected, is used to display the current AutoTEC Software version.



SYSTEM SETUP

When selected, is used to set up alarm volume, alarm sound, end of process sound, current year, date and time, and institution name.



SHUT DOWN

When selected, is used to shut down the AutoTEC Software applications, Windows operating system PC, and instrument.



COOL DOWN Mode

OR



WARM UP Mode

When selected, will either shut down all AutoTEC heaters or start warming up all AutoTEC heaters. When in Cool Down mode, the AutoTEC Software application is still operational, but the system cannot embed cassettes until all the heaters are up to operating temperature.



CLEAN GRIPPER ARMS

When selected, is used to request the gripper arms to be moved to above base mold #5 position, to allow operator easy access to clean the gripper arms.

CUSTOMIZATION OF SETTINGS

ERROR LOG Screen

ERROR LOG screen is displayed, when the ERROR LOG tab is selected (Figure 3-E).

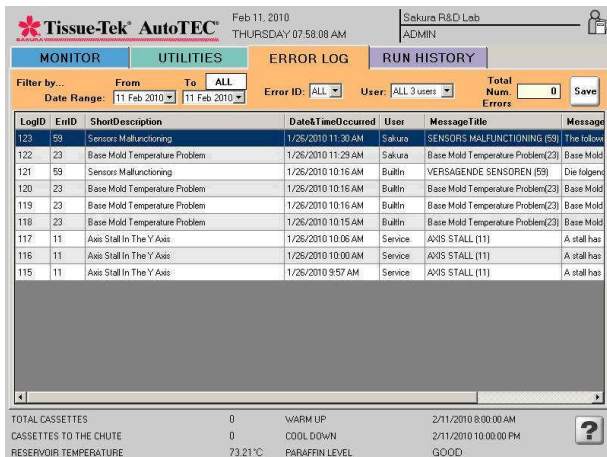


Figure 3-E

- Up to date accumulated error messages can be sorted by date ranges, error code ID#, and User name.
- Total number of errors in the sorted log.
- **SAVE** button. When selected, will save sorted error log to an external memory stick.

RUN HISTORY Screen

RUN HISTORY screen is displayed, when the RUN HISTORY tab is selected (Figure 3-F).

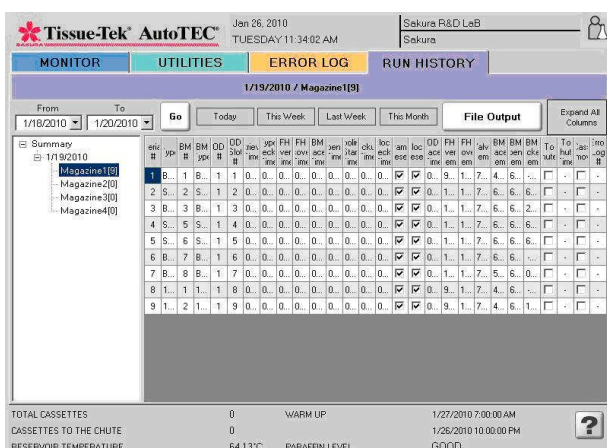


Figure 3-F

- Displays information on the cassettes ran, based on the following selected criteria:
 - Date ranges
 - Today, This Week, Last Week, or this month.
- **File Output** button. When selected, will save selected run history to an external memory stick.
- **Expand All Columns** button. When selected, toggles the display to show all columns in one screen or to show all information inside each column (requires user to use the horizontal scroll bar to see all displayed information).

SERVICE Screen

(Only available with Service level login)*

SERVICE screen is displayed, when the SERVICE tab is selected (Figure 3-G).

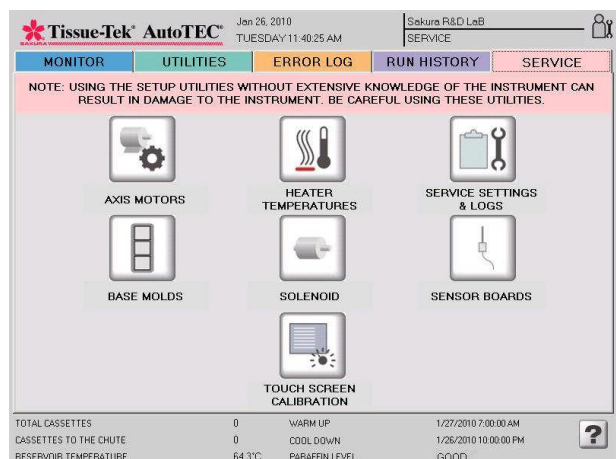


Figure 3-G

*Please refer to the Service Manual for more details.

Map of Interface Screens

Figure 3-H illustrates the general structure of the interface available for an administrator level clearance, showing screens accessible from the Monitor screen.

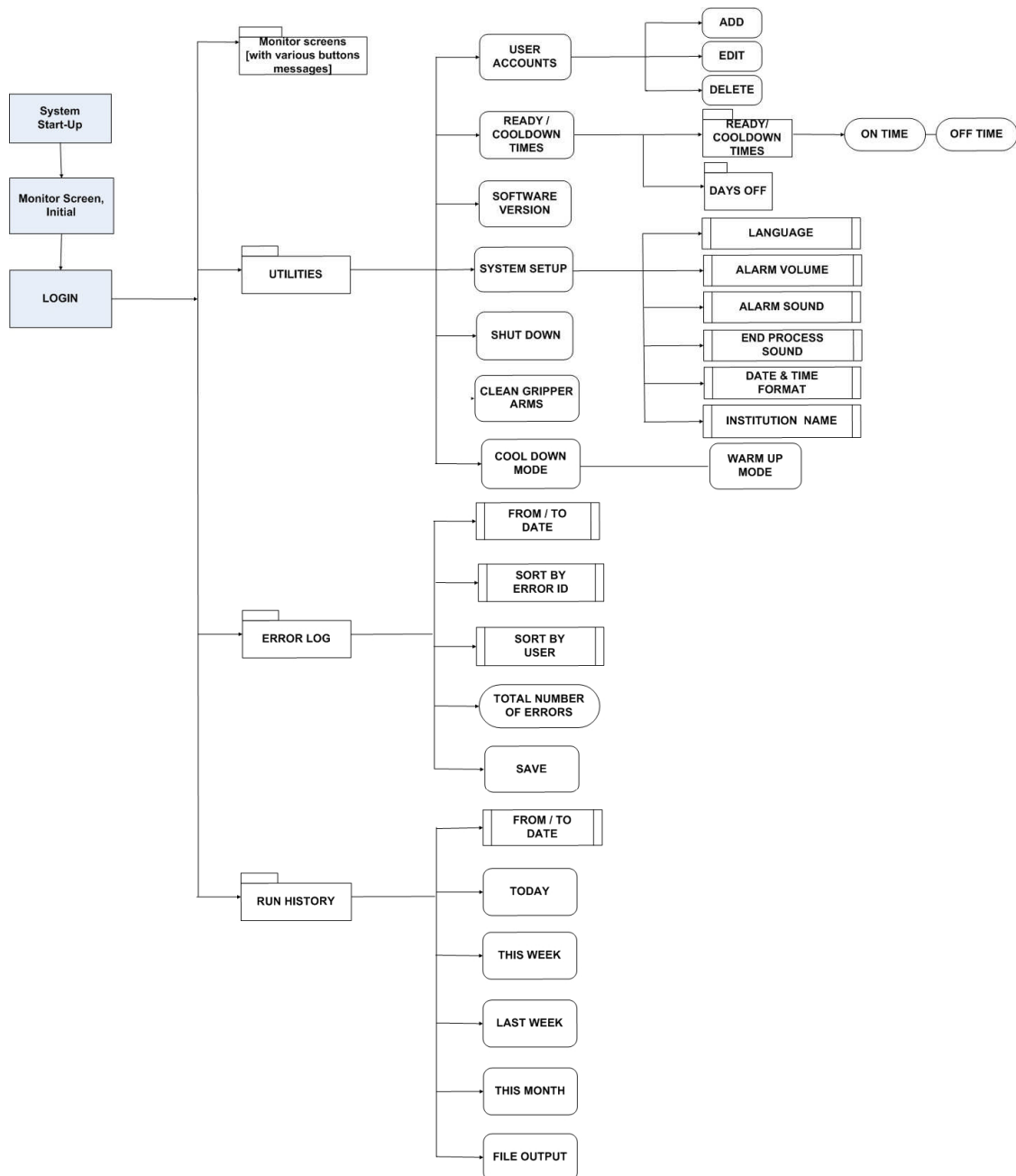


Figure 3-H

CUSTOMIZATION OF SETTINGS

The Tissue-Tek® AutoTEC® allows for the customization of a number of system options and operating parameters to suit the requirements of a given laboratory.

The UTILITIES screen provides the means of viewing the current system settings, of selecting and configuring system options, and specifying the desired values for user-configurable operating parameters.

This section provides the procedures to perform initial setup.

Perform the following setup procedures before routinely using the Tissue-Tek AutoTEC system. In addition, perform these procedures as needed to reset the clock, add or remove users, change automatic start-up and cool-down times, etc.

Access Levels

A user can have one of two access levels:

- **Administrator** — Users with administrative status can navigate through all available screens to perform functions including system setup, run history tracking, and start up and cool down programming.
- **Operator** — Users with operator status can only navigate the main screens, general operational functions, and some utilities screens. See page 3.7 for details.

Up to 55 names and passwords can be active at any time – 13 Administrators, and 42 Operators. The type of user currently logged in is identified by an icon that appears in the top right corner of each screen:



Administrator



Operator

Page 3.14, User Accounts, describes how to set up names and passwords.

Accessing the UTILITIES Menu

NOTE: Login as an Administrator in order to set up or modify system settings through the UTILITIES menu.

Select the **LOG IN** button to access the Enter Password keypad. A valid password must be entered to Log In and to enable all the buttons and tabs (Figure 3-I).



Figure 3-I: Password keypad

NOTE: The factory default operator level PASSWORD is 100000.

NOTE: The factory default Administrator level PASSWORD is 000001.

NOTE: As soon as an administrator level password is set up (see User Accounts on page 3.13), this factory default password should be deleted or modified.

Following a successful login, the Initial MONITOR screen will appear (Figure 3-J).

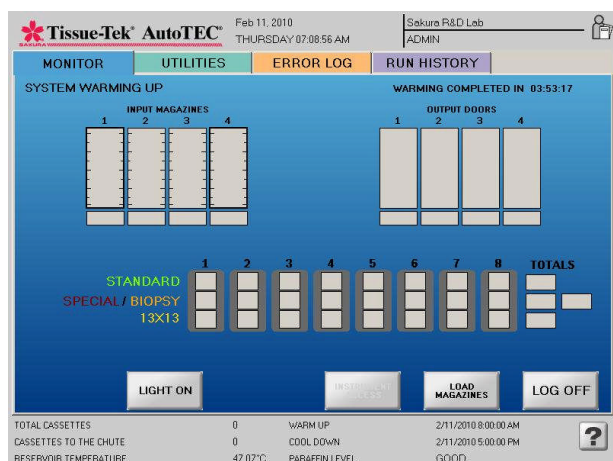


Figure 3-J: MONITOR screen

Touch the **UTILITIES** tab to access the Utilities Selection screen. This screen is always accessible, but not all features can be used while the AutoTEC is running.

Configuring System Settings

Figure 3-K shows the Utilities screen as viewed by an administrator. This screen gives access to various system utilities. Touching an icon accesses the associated utility. Icons for utilities inaccessible during AutoTEC operation display in gray.

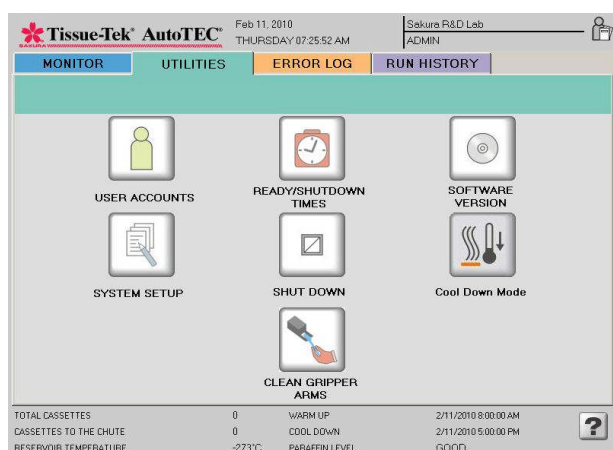


Figure 3-K: Utilities Selection screen: Administrator

Administrator level access allows access to all utility functions.

Operator level access is restricted to the following functions, some being on a view only basis. These are:

Full Access:

- UTILITIES
 - o Ready / Cool Down Times
 - o Shut Down
 - o Cool Down Mode / Warm Up Mode
 - o Clean Gripper Arms
- Error Log
- Run History

View Only:

- UTILITIES
 - o User Accounts
 - o Software Version
 - o System Setup

NOTE: Icons unavailable to operator-level users or inaccessible during AutoTEC operation are displayed in gray.

NOTE: To avoid data corruption, some of the parameters cannot be changed while the AutoTEC is in operating mode (running or ready to run). These restricted parameters are:

- Setting the completion of the four hour warm up routine automatically at specific times (ready times) on specific days
- Setting of the automatic cool down at specific times on specific days
- Override of the programmed ready and cool down times for scheduled days off such as holidays or vacation days
- Creation of user names and passwords
- Setting of user-defined names
- Setting of system parameters

The four operator accessible utility screens are reviewed first in the following pages, followed by the review of the three screens which can only be accessed by an administrator. The ERROR LOG and RUN HISTORY screens are covered in Section 4, Operation.

CUSTOMIZATION OF SETTINGS



Ready/Cool Down Times

Operators can program automatic timers to initiate the four-hour warm up routine at specific times on specific days so that the AutoTEC will be ready for the first run when the shift begins or when operators are ready to start. The time entered specifies when the system will be ready for embedding (plus the 15-minute magazine-warming process). System warm up will begin four hours before the time entered for the ON time on the Ready/Cool Down Times screen.

Automatic timers are set on the Ready/Cool Down Times screen (Figure 3-L):

- Select **AUTO** radial button.
- Select **READY/COOL DOWN TIMES** tab.
- To set a time, touch in an ON TIME or OFF TIME field. Use the keypad to enter a time (in either 12- or 24-hour format, depending on the parameter selected in the System Setup screen); the entry will appear in the selected field. Touch the ENTER button to transfer the time to the ON or OFF TIME field.
- To change a field to **NOT USED**, touch in that field, then touch the **NOT USED** button.

After all times have been entered, check that they are correct, and then touch the **SAVE AND EXIT** button to return to the System Setup screen.

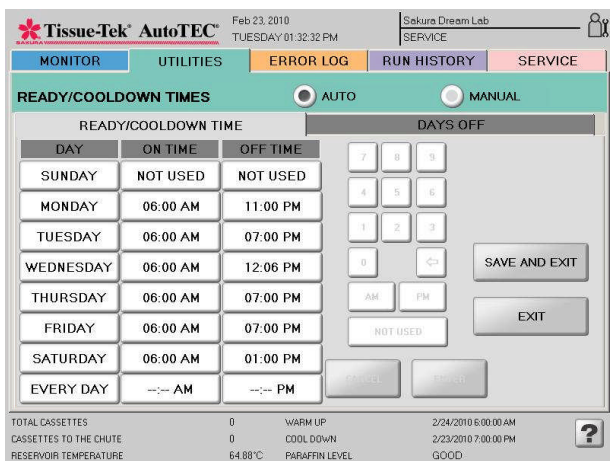


Figure 3-L: Ready/Cool Down Times screen

NOTE: The times set in this screen will repeat weekly *unless* Days Off is specified.

NOTE: In Auto At least one ON TIME and one OFF TIME must be set.

NOTE: To control the Ready/Cool Down time manually, select the **MANUAL** radial button. NO TIME SET appears for the WARM UP and COOL DOWN time in the MONITOR screen.

Days Off Selection

Use the Days Off screen to override the automatic timers on specific days that the AutoTEC will not be operating due to holidays, vacations, or other scheduled days off. On days selected here, the AutoTEC will not automatically start its warm up procedure.

To schedule a day off (Figure 3-M):

1. Select the **DAYS OFF** tab.
2. Use the arrow buttons located in the upper-left and upper-right corners of the calendar to change the month.
3. Touch on the date on the calendar to set as off. The chosen date will be circled in red on the calendar, as will any other days off in the displayed month.

To delete a date and restore it to a working day:

- Either touch the date on the calendar, the red circle will disappear.

When all days off have been scheduled, touch the **SAVE AND EXIT** button.

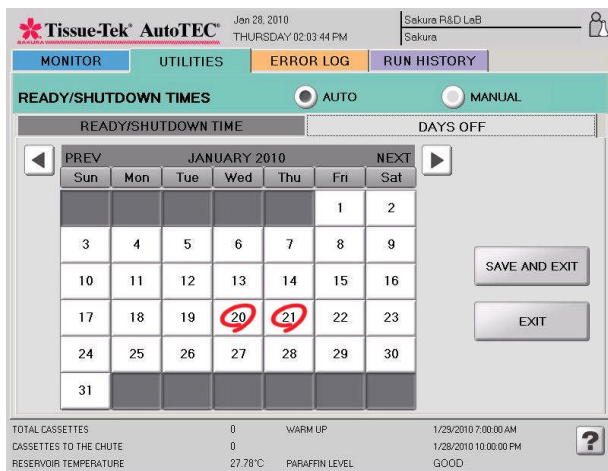


Figure 3-M: Days Off screen



Shut Down

Touch the **Shut Down** icon from the **Utilities** Selection screen to initiate system shut down. When the **Shut Down** icon is touched, a prompt (Figure 3-N) appears requesting confirmation that the system should shut down.



Figure 3-N: Shutdown Confirmation Prompt

NOTE: When shut down, is confirmed, the AutoTEC program, Window operating system, and PC will completely turn off. To restart the AutoTEC Software, the operator needs to cycle the AC circuit breaker OFF/ON. Shut down is equivalent to a hard reset and restart of the AutoTEC hardware and software.

NOTE: Before the AutoTEC actually starts the shut down process; a message will be prompted to the operator to remove all magazines inside the Input Doors.



Cool Down Mode

Touch the **Cool Down mode** icon from the Utilities Selection screen to initiate system cool down. When the **Cool Down mode** icon is touched, a prompt (Figure 3-O) appears requesting confirmation that the system should cool down and allow the paraffin to cool.

NOTE: In the **Cool Down** mode, the system cannot embed cassettes. A warm up time of up to 4 hours will be needed before embedding can start.

NOTE: If a Cool Down time was programmed for that day, this forced cool down will override that time for the current day only. The programmed time will remain active for future days. Refer to page 3.8 about how to program cool down times.

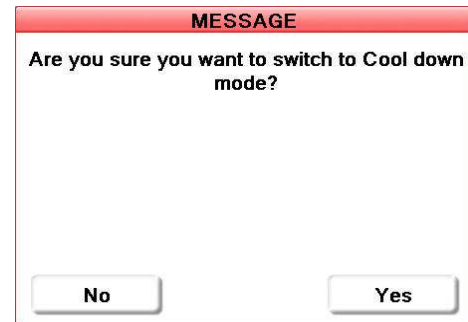


Figure 3-O: Cool Down Confirmation Prompt

Once this prompt is acknowledged, another (Figure 3-P) appears requesting that all magazines be removed from the input door.



Figure 3-P: Magazine Removal Prompt

The AutoTEC will not cool down until the input door is cleared of magazines and closed, and the on-screen prompt is acknowledged. The Utilities screen continues to display during this process.

CUSTOMIZATION OF SETTINGS

Touch the **MONITOR** tab to display the **MONITOR** screen. **COOL DOWN** will be displayed at the upper-left corner of the screen, as seen in Figure 3-Q.

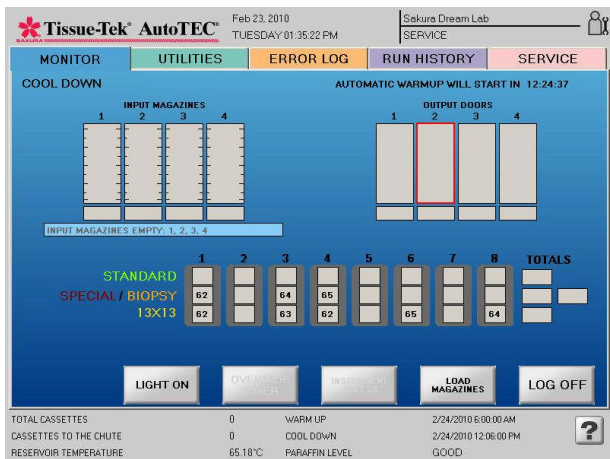


Figure 3-Q: Run screen, Cool Down Mode

A count-down timer in the upper-right corner will indicate the remaining time until the automatic start-up sequence is to begin. These times can be set by an Administrator as described on page 3.8.

The AutoTEC will exit the **Cool Down** mode and begin the 4-hour warm up process, when the auto start time begins or when the operator touches the **WARM UP** mode button in the **UTILITIES** screen.



Software Version

The **Software Version** screen displays the software version in use, and the serial number of the AutoTEC. Record this information at installation and each time the software version is updated (Figure 3-R).

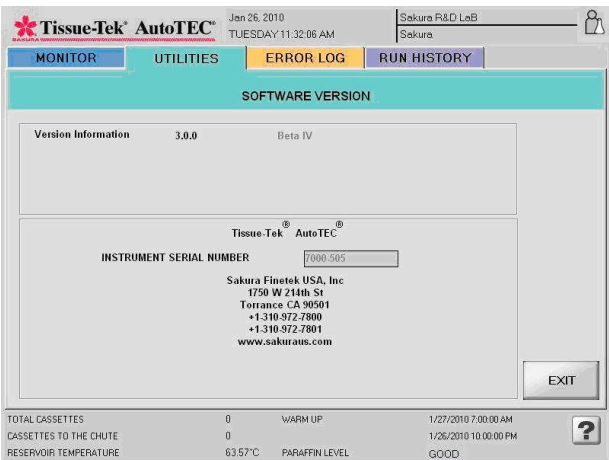


Figure 3-R: Software Version screen



Clean Gripper Arms

Touch the **Clean Gripper Arms** icon, to request the gripper arms to be moved to the area above the base mold #5 position, allowing operators easy access to clean the gripper arms.



System Setup

The **System Setup** screen (Figure 3-S) enables the administrator to set a variety of system parameters. Operators can only view the operator view of the System Setup screen (Figure 3-T).

Figure 3-S: Administrator view, System Setup screen

Figure 3-T: Operator view of the System Setup screen

To set system parameters:

The **RESTORE DEFAULTS** restores all settings to their defaults.

Set-up parameters, defaults, and functions are as follows:

Parameter	Default	Function
Alarm Volume	High	Sets the volume level for alarms
Alarm Sound	Alarm 4	Selects alarm sound from seven options
End Process Sound	End Process 5	Sets sound for end process indication from seven options
Date and Time	--	Enables the date and time to be set

The following pages review in details each of the user-defined parameters.

Languages Setup

As shown in Figure 3-U, in addition to English, the following 15 language choices can be selected: French, Dutch, Spanish, Italian, German, Swedish, Finnish, Danish, Greek, Norwegian, Czech, Russian, Japanese, Korean, and Portuguese.

Figure 3-U: Languages Setup screen

CUSTOMIZATION OF SETTINGS

Once a language selection is made from the drop down list, the System Setup screen will be displayed in the selected language immediately (Figure 3-V). However, the selection is not saved until the “SAVE AND EXIT” button is pressed.

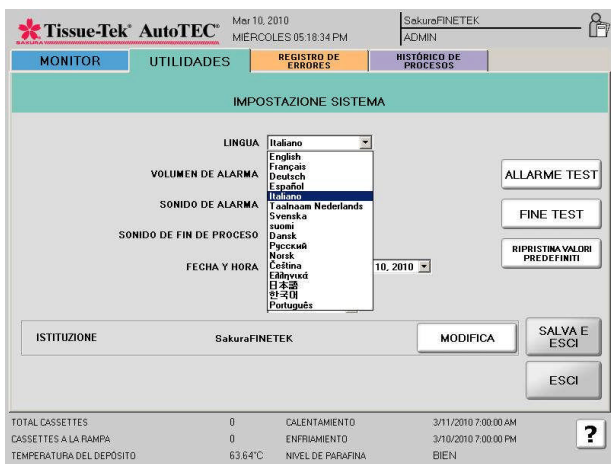


Figure 3-V: System Setup screen in selected language

The selected language will be used in all other screens. It will take a few seconds for all the screens to be updated (Figure 3-W).

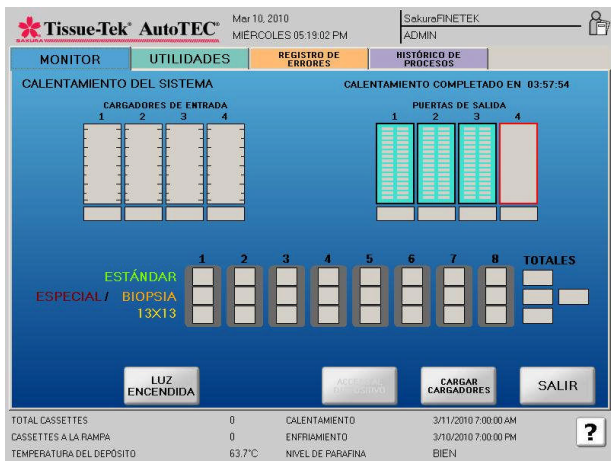


Figure 3-W: Screen Updated in Selected Language

Audible Alarm Setup

As shown in Figure 3-X, System Setup screen, there are three alarm attributes that can be modified. Select between three volume levels (High, Middle, Low), eight different alarm sounds labeled as Alarm 1 through Alarm 8, and eight different end of process sounds labeled as End Process 1 through End Process 8.

Select the down arrow to activate the pull down list then scroll to highlight the selection. The following screen shows how to set Alarm volume to **LOW**.

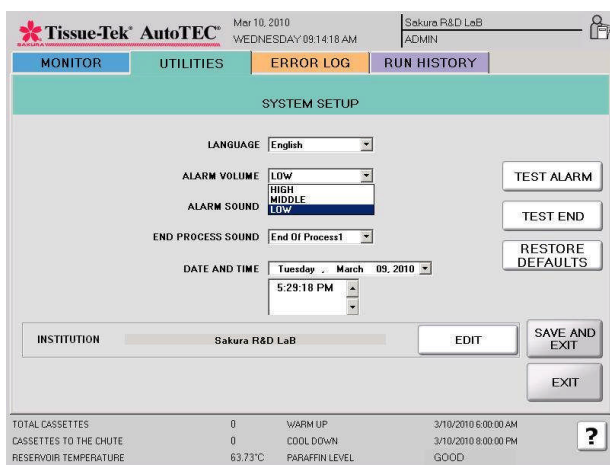


Figure 3-X: System Setup screen, Alarm Volume

Select the **TEST ALARM** or **TEST END PROC** button will output an audible sample of the current selection.

Select **SAVE AND EXIT** to save the changes. Select **EXIT** to abort the changes.

DATE and TIME Setup

For current **DATE** setting, select the **DATE** down arrow to activate the calendar screen. Select the correct date (Figure 3-Y).

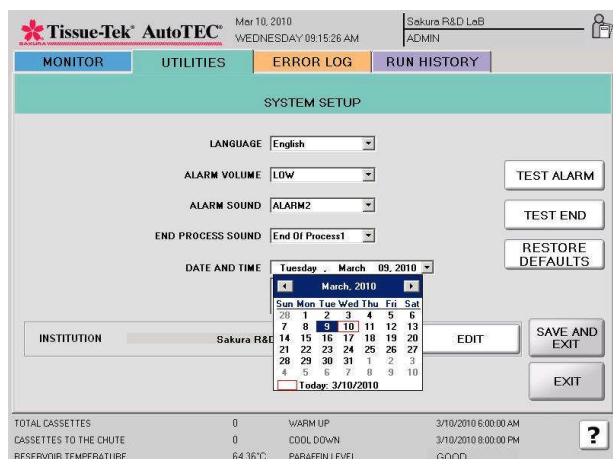


Figure 3-Y: System Setup screen, Date

For current **TIME** setting, highlight one of the three time fields for **Hours**, **Minutes**, and **Seconds**, use the **UP** or **DOWN** arrow to increment or decrement the highlighted selection (Figure 3-Z).

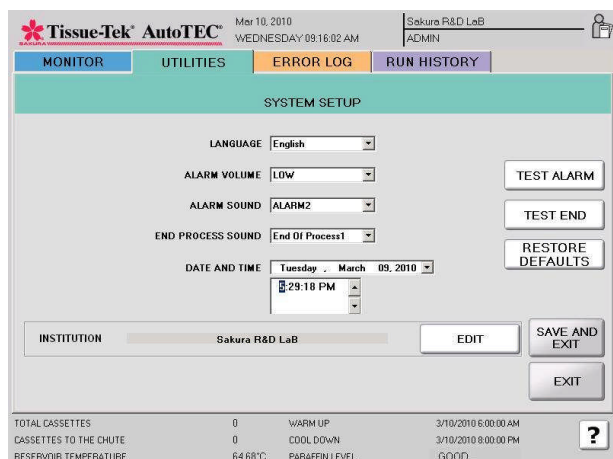


Figure 3-Z: System Setup screen, Time

Select **SAVE AND EXIT** to save the changes. Select **EXIT** to abort the changes.

NOTE: Time can only be changed, when AutoTEC is idling and there is no timer running, such as the 4 Hr. warming up timer.

INSTITUTION Setup

Select **EDIT** to bring up **CHANGE INSTITUTION NAME** keyboard (Figure 3-AA). Use **BACKSPACE** to clear current entry. Use keypads to enter new name. Use **SHIFT** to change letter fonts. Select to **ENTER** to confirm and save current changes.

The new institution name will be updated immediately and can be seen at the upper right corner of the LCD display.

Select **EXIT** to return to UTILITIES screen.

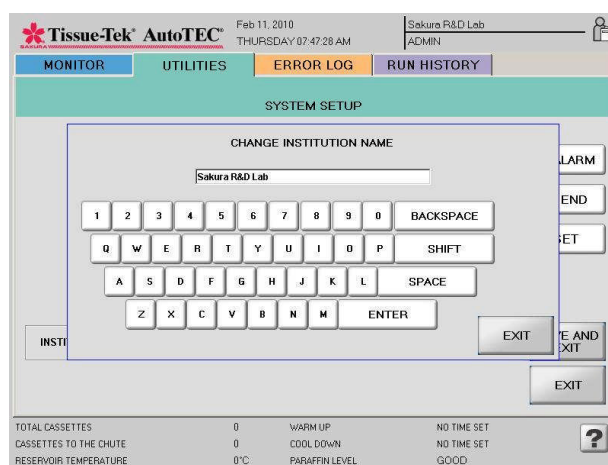


Figure 3-AA: System Setup, Keyboard

CUSTOMIZATION OF SETTINGS



User Accounts

From the Utilities screen (Figure 3-BB), touch the **USER ACCOUNTS** icon to bring up **MANAGE USER ACCOUNTS** screen. A total of up to 13 Administrators and 42 Operators can be set up.

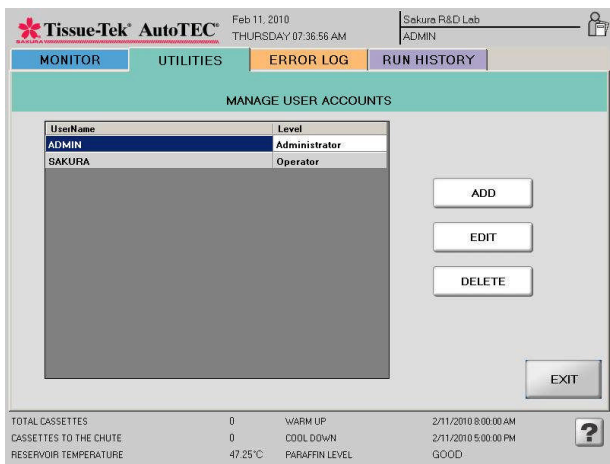


Figure 3-BB: Utilities screen

Select **ADD** to add a new user. Use the keyboard display to type in the information for the new user (Figure 3-CC).

Highlight a user from the UserName list then select the **EDIT** to edit an existing user. Highlight a user from the UserName list then select the **DELETE** to delete an existing user.

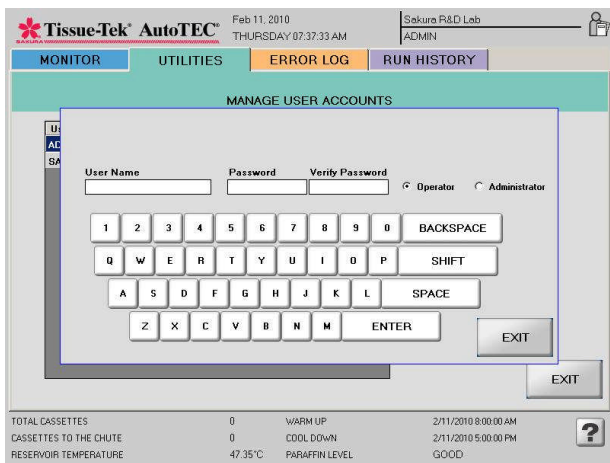


Figure 3-CC: Add a new user

NOTE: Passwords and user names can only have a maximum of 8 characters.

NOTE: Administrators may change or delete passwords and user names but passwords are never displayed. If an operator forgets their password, it can be reset.

Touch the **User Name**, **Password**, **Verify Password** fields and use the display keyboard to type a name and passwords (Figure 3-DD).

NOTE: The user name and passwords are not case sensitive.

NOTE: Each entered password letter is displayed as “*”.

NOTE: Entries are not saved until **ENTER** is selected from the Passwords screen.

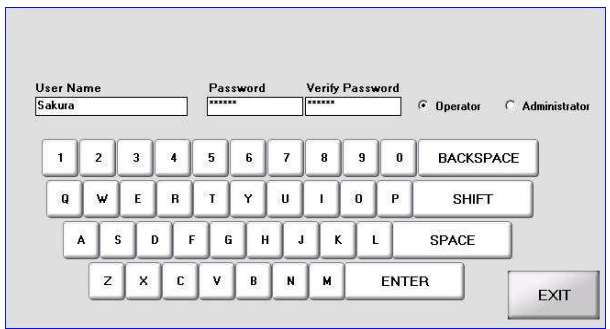


Figure 3-DD: User Name and Password Entry screen

Exporting Data

The system allows sending reports and files to a flash drive. The connection ports location can be seen in figure 1-B, location 8. If a flash drive is connected in the USB port the data will be transferred to that drive.

Error Log

By selecting the **ERROR LOG** tab, the **ERROR LOG** screen is displayed (Figure 3-EE).

The error log displays chronological information about system errors and events that occur, including a number and description, run number, date and time of the error or event. The total numbers of selected errors are displayed inside the **Total Num Error** box.

Figure 3-EE: Error Log screen

Error log can be sorted in the following ways to help viewing.

- **By Date Ranges.** Select the pull down arrow for the **From** and **To** date to activate the date selection calendar (Figure 3-FF).

Figure 3-FF

- **By Error ID.** Select the Error ID pull down arrow to display the pull down menu. Scroll to the selection (Figure 3-GG).

Figure 3-GG

- **By User.** Select the User pull down arrow to display the pull down menu. Scroll to the selection (Figure 3-HH).

Figure 3-HH

NOTE: Built in user, is created to automatically log events that happen when no user is logged in.

CUSTOMIZATION OF SETTINGS

- The **ALL** button will display a listing of **ALL** errors that are logged in the instrument, from the very first one registered till the last one. When this button is pressed, the **From** and **To** dates will change accordingly, and the **ALL** button will also change to display Today, instead (Figure 3-II).

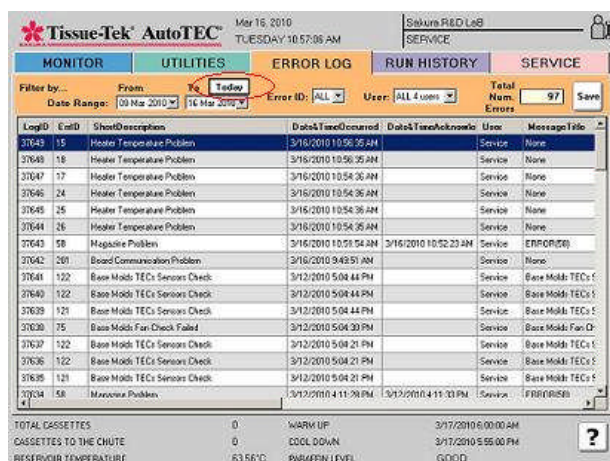


Figure 3-II

When this **Today** button is pressed, the error listing will instead display only the errors that have occurred on the current date, if any. Also, both the **From** and **To** dates will show today's date, and the **Today** button will toggle back to an **ALL** button.

By selecting the **Save** button; the selected Error log can be transferred to a Flash drive (Figure 3-JJ).

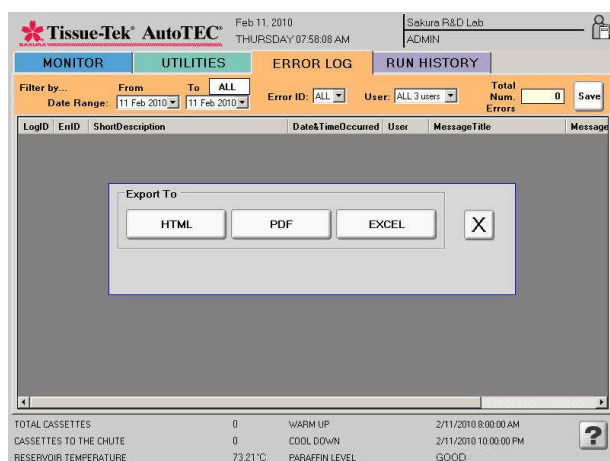


Figure 3-JJ

Output files can be saved in any one of the three formats, HTML, PDF, or EXCEL to help in organizing the collected data.

NOTE: Internal events are recorded in the Error Log but are not considered errors which require corrective action. An example of such an event is the second or third attempt of the gripper to pick up a framed cassette.

Refer to Section 6, entitled Troubleshooting for error recovery information.

RUN HISTORY

By selecting the **RUN HISTORY** tab, the **RUN HISTORY** screen is displayed (Figure 3-KK).

The RUN HISTORY displays chronological run information of the selected days.

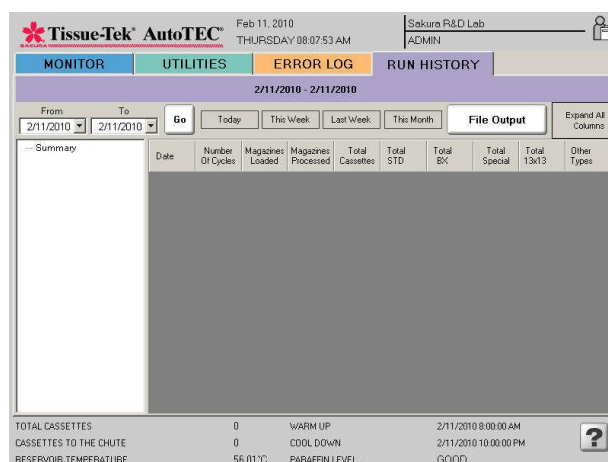


Figure 3-KK: Run History screen

Run history display choices are following:

- By selecting **Today** button, see today's run.
- By selecting **This Week** button, see this week from Sunday to Saturday's runs.
- By selecting **Last Week** button, see last week's Sunday to Saturday's runs.
- By selecting **This Month** button, see this month's run.
- By specifying a date range, using the **From** and **To** pull down arrow to activate the date selection calendar.

Section 3

NOTE: When using date range; after the date selections, select the **Go** button first to update the display.

The **Summary** displays the days selected and the total numbers of cycles, magazines, cassettes, types of cassettes, etc (Figures 3-LL and 3-MM).

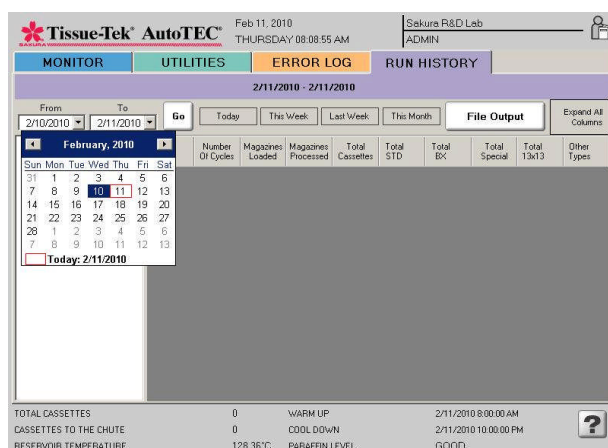


Figure 3-LL: Summary page

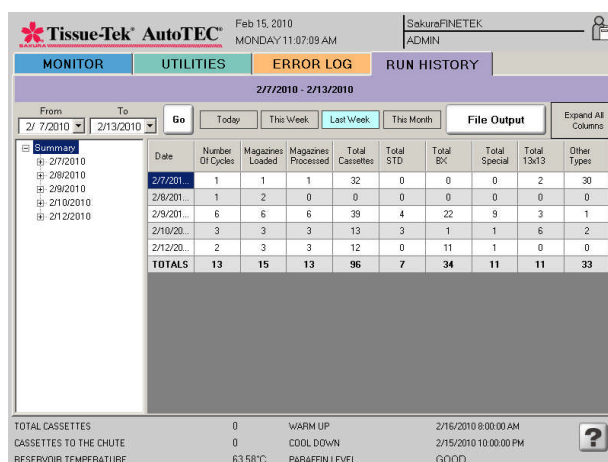


Figure 3-MM: Summary page

By selecting a **date** from the summary screen, details of all the magazines ran on that day are displayed (Figure 3-NN).

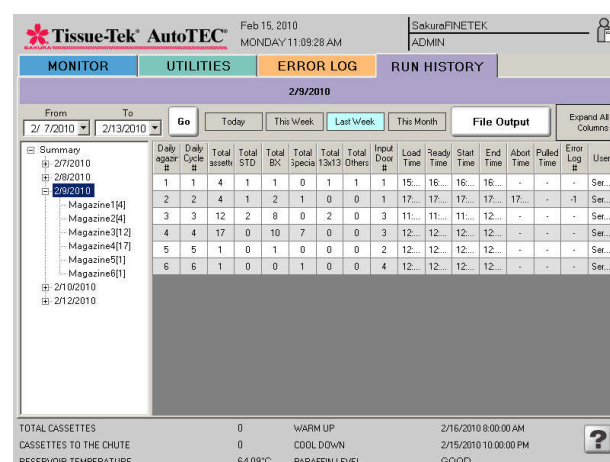


Figure 3-NN: One day view

By selecting a **magazine** from the summary screen, details of all the cassettes in this magazine are displayed (Figure 3-00).

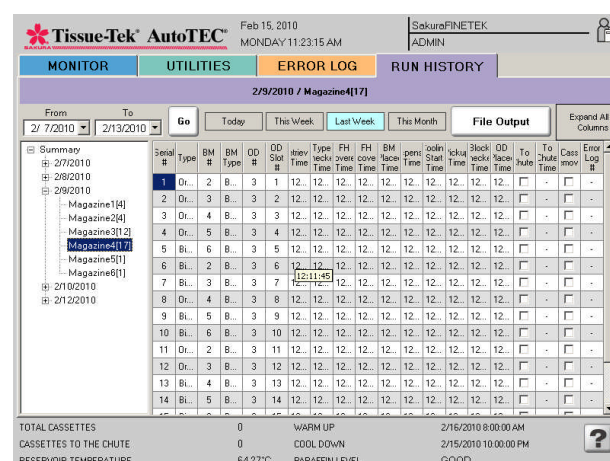


Figure 3-00: One magazine view.

CUSTOMIZATION OF SETTINGS

Displayed columns can be toggled between, expanded, or compressed to fit the LCD display area, by selecting the **Expand All Columns** button (Figure 3-PP).

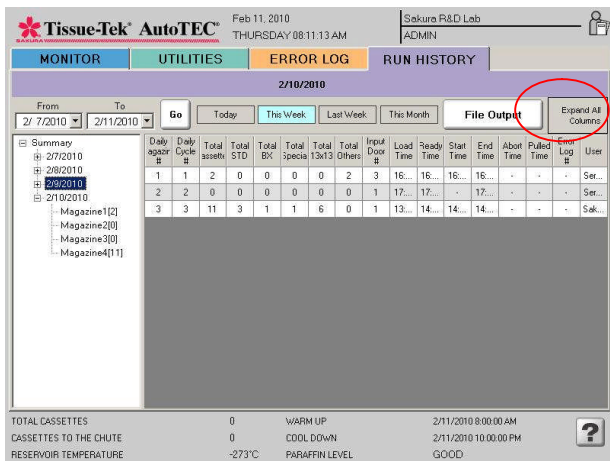


Figure 3-PP: Expand view

The run history display can be rearranged by selecting a column, dragging it, and dropping it at a new location (Figure 3-QQ).

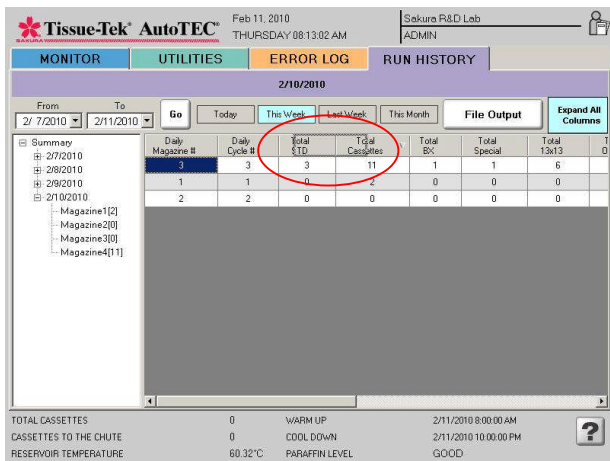


Figure 3-QQ: Dragging a column to a new location

By selecting the **File Output** button; the selected run history can be transferred to a flash drive (Figure 3-RR).

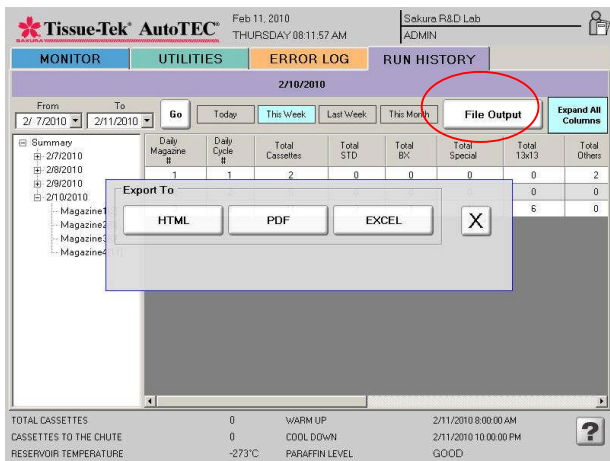


Figure 3-RR: File Output

Output files can be saved in any one of the three formats, HTML, PDF, or EXCEL to help in organizing the collected data.

OPERATION

Initial Start-Up

To start the Tissue-Tek® AutoTEC® manually, such as when using it for the first time, follow this procedure:

1. Use the main power switch located on the lower-right side panel to turn the AutoTEC on. The computer will start automatically. After the software has completed the loading process, the Monitor screen will display (Figure 4-A).

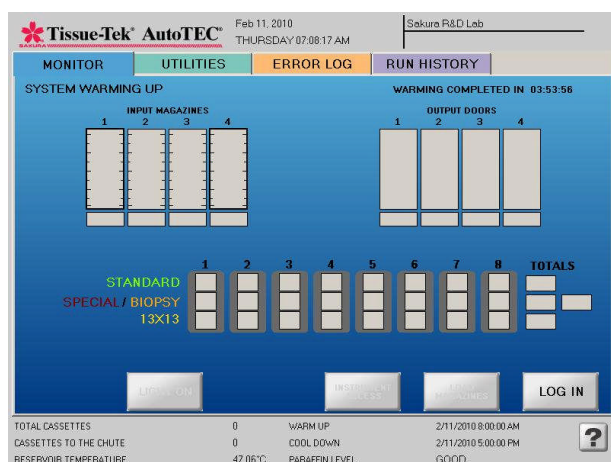


Figure 4-A: System Start Up screen

2. Select the **LOG IN** button to access the **ENTER PASSWORD** screen (Figure 4-B).



Figure 4-B: Log In screen

NOTE: Refer to page 3.14, User Accounts to set up the passwords.

3. Use the keypad display to type in the password.
4. Select **ENTER** when done.
5. The Monitor screen is displayed with a **LOG OFF** button (Figure 4-C).

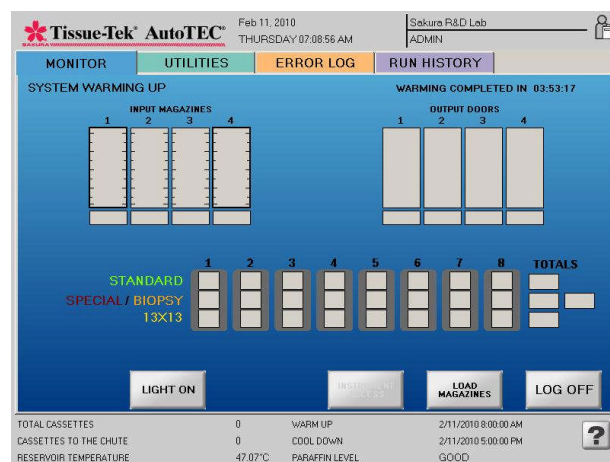


Figure 4-C

Typical Operating Sequence

A typical operating sequence for the Tissue-Tek AutoTEC is as follows:

- Warm Up
 - System perform automatic self checks
- Operation
 - Preliminary checks
 - Verify the proper placement of Paraform cassettes into the magazines
 - Insert magazines inside the input door
 - Embed Paraform Cassettes
 - Remove output doors containing embedded blocks
 - Prepare for the next run
 - End of operations
- Review Reports
- Perform maintenance as required
- Cool Down

OPERATION

Routine Operation

Warm Up

The Tissue-Tek AutoTEC requires a four-hour warm up time at initial start up or if it was cooled down. The warm up period can be programmed to start automatically at a set time. Following warm up, the Tissue-Tek AutoTEC is in Operating mode, ready to embed. A valid user must be logged in to start embedding.

Preliminary Checks

Remove, then either clean or replace the paraffin trough (Figure 1-C, Location 12). Place trough back into position before beginning operation.

Ensure that paraffin levels are adequate prior to starting operations. When adding paraffin to the reservoir during normal hours of operation, use molten paraffin; do not overfill the reservoir. Use the paraffin fill gauge, shown in Figure 1-J, as a guide. At the end of the work day, paraffin pellets may be added.

Only Tissue-Tek® Paraform® Sectionable Cassettes and Tissue-Tek® Paraform® Processing/Embedding Medium, Formula 3 (product code 7052) can be used in the AutoTEC. See Section 7, Service and Replacement Parts for information about how to order cassettes and additional paraffin.

Confirm that the output doors are empty, and that the front and rear access doors are closed and latched.

Depending on the initial thermal state of the system and the room temperature, all internal components may reach temperature before the 4 hour period has elapsed. At that point, the **VERRIDE TIMER** button will display (Figure 4-D). The operator has the choice to either wait for the 4 hour cycle to complete or to touch the **VERRIDE TIMER** button to force the system to the ready state. In either case, the **VERRIDE TIMER** button disappears.

If the input door heaters are at temperature (typically 15 to 30 minutes after warm up begins), the **LOAD MAGAZINES** button will display. Because the rest of the instrument is not up to temperature, do not place cassettes in the instrument until about 30 minutes prior to the end of the warm up period, to avoid leaving tissues exposed to heat for too long.

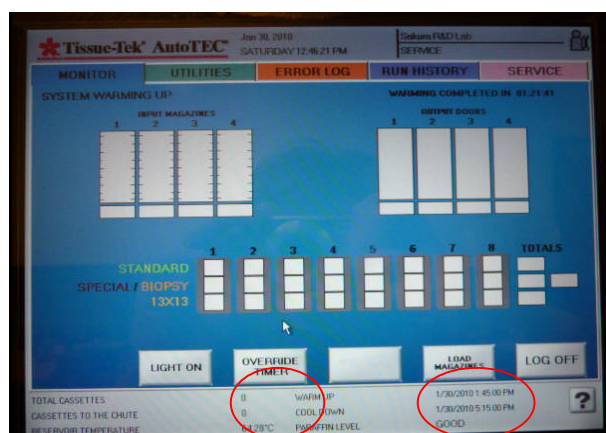


Figure 4-D: Initial Run screen (warm up cycle with system up to temperature)

It is recommended to cool down the instrument (manually or automatically) at the end of the day, to leave instrument AC power switch on, and to program a Ready Time that will ensure the system is ready when the laboratory operation begins.

For example, if the laboratory opens at 7AM, a Ready Time set at 7AM will guarantee that the warm up cycles starts at 3AM and is completed by 7AM, at the latest. In that case, after a successful log in, the Monitor screen will not have any timer indication on the upper right corner, and the only buttons available will be **LOAD MAGAZINES**, **LIGHT ON**, and **LOG OFF**. The instrument is then ready to receive cassettes and embed them.

Touching **LOAD MAGAZINES** button will give access to the input door. An on-screen message will confirm that the input door is ready to be opened.

Load Magazines

Usually, the Paraform Cassettes are assembled and inserted into the magazines at the grossing station. Magazines are standard- or Tissue-Tek® Xpress® Rapid Tissue Processor- type. Standard magazines can hold up to 32 Paraform® cassettes. These magazines are compatible with the Tissue-Tek® VIP® tissue processors; Xpress magazines can hold up to 20 Paraform® Cassettes. Figure 4-E shows an example of each type of magazine.

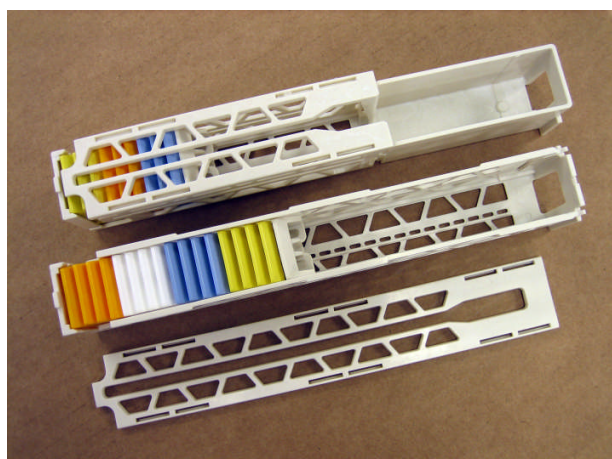


Figure 4-E: Xpress Magazine with Adapter and Lid, Standard Magazine with Lid removed



Figure 4-F: Cassette Retainer in position

To load magazines into the input door, follow these instructions:

1. Properly assembled and placed frame/cassettes inside the magazine are necessary for uninterrupted embedding operation. Please verify:
 - a. Check the orientation of cassettes in the magazines: The top sides should be facing up, and the angled writing surfaces of the frames should be toward the magazine cover.
 - b. Ensure that all frames are parallel – none fallen or tipped backward.
 - c. When holding a magazine filled with frames and viewing from the sides, there should be no gap between the frames. Any gap found between frames, can be an indications of not properly closed cassette lid or cassette is pushed through the frame. Open the magazine lid and investigate the causes of the gap and correct if necessary. Ensure that cassettes are properly inserted in the frame with lids securely closed.
 - d. Make sure the magazine retainer can slide one space above the topmost frame in the magazine. The retainer is seen in the magazine shown in Figure 4-F.
 - e. Ensure that the magazine lid is closed.
2. Touch the **LOAD MAGAZINES** button. A message will appear indicating that the system is preparing the input door to be opened.
3. When the input door is ready to be opened “**Okay to open input door**” will appear in the message area, and a two-minute timer will display at upper right. If the door is not opened in time, the system will assume that access is not required and return to the state it was in prior to the **LOAD MAGAZINES** request.
4. Open the input door by turning the knob counter clockwise (Figure 4-G).

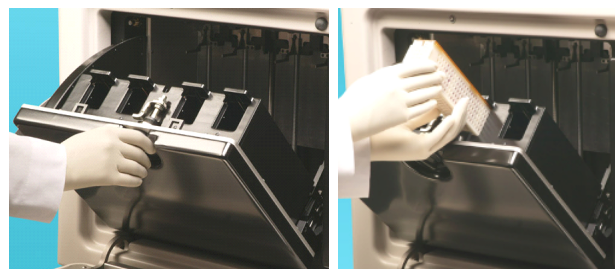


Figure 4-G: Loading a Magazine

OPERATION

5. Hold the magazine upright against paper towels or other absorbent material to allow excess paraffin to drain off the magazine before placing it in the AutoTEC.
6. Insert the loaded magazine/s into the input door and press each of them down as far as possible.

NOTE: After the magazine is inserted, verify the magazine lid is popped open for the Standard magazine. The Xpress magazine is shorter so the top of the lid cannot be seen; however, as the Xpress magazine is sliding down into the ID, a slight resistance should be felt near the bottom of the ID insertion, as the lid slides open.

NOTE: If the door is shut then immediately re-opened, the system will not sense the addition of further magazines. To continue to add magazines, close the door and touch **CONTINUE** in the prompt (Figure 4-H) that appears as soon as the door is closed, then touch the **LOAD MAGAZINES** button again to insert more magazines. The cassette count for a given input magazine is cleared when that magazine is removed from the door. The count can also be reset immediately by logging off the system and logging in again, with magazines left inside the input door.

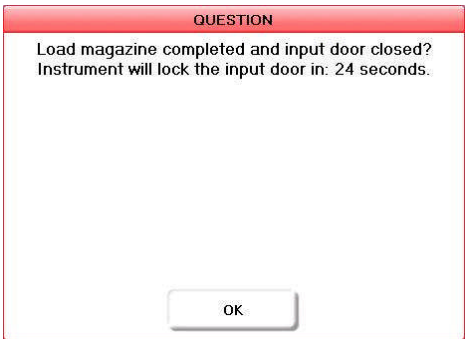


Figure 4-H: Input Door Activity Acknowledgement

7. Securely close the input door by rotating the knob clockwise and touch **CONTINUE** in the on-screen prompt. The Warming Cassettes screen displays and the 15-minute cassette warming process begins. This warm up time is required to ensure there is no solid or semi-solid paraffin in the magazine that could interfere with the action of the robotic arm. If magazines were previously inserted and have reached temperature, the system will immediately start or continue to embed these cassettes. By the time these cassettes are completed, the newly

inserted magazines will likely be ready for embedding for maximum efficiency.

The Warming Cassettes screen (Figure 4-I) specifically displays magazines in their 15-minute cassette warm up period. In this figure, as indicated by the red highlights, two magazines have been loaded and will reach temperature in 13 minutes 5 seconds as shown in the upper right corner. A complete description of Run screen layout and color coding is given on the next page.

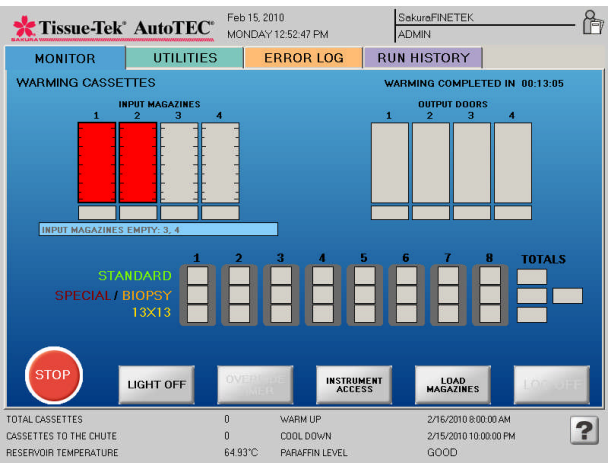


Figure 4-I: Run screen, Warming Cassettes

NOTE: To maximize system throughput and efficiency, remove any empty magazines and replace them with filled ones as they become available. Operating in this manner will always guarantee that the 15-minute cassette warm up time is completed by the time the instrument robotics are ready to embed these cassettes.

Run Screen Layout

The Run Screen layout is consistent through all phases of system embedding. As shown in figure 4-J, the four input magazines are shown on the left, while the four output doors are shown on the right; reflecting the same physical view as if the operator was standing in front of the system. The three banks of base molds are depicted below the magazines and doors. The totals shown on the right of the base molds indicate how many of each type of cassettes have been embedded so far.

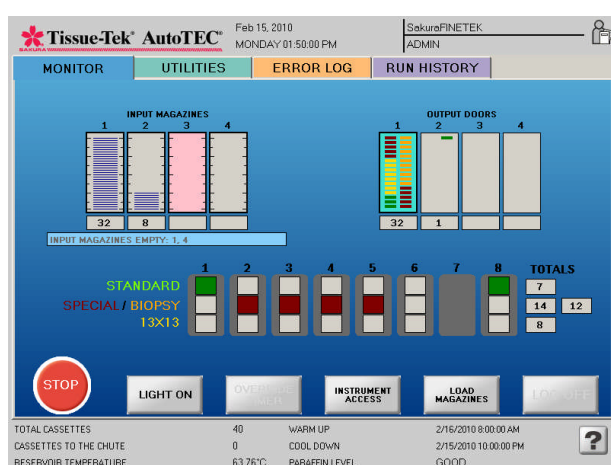


Figure 4-J: Run screen layout

Run Screen Color-Coding

The Run screen displays the status of the magazines, base molds, and output doors using the following color-coding:

NOTE: As a general rule for the input magazines and output doors, a dark border indicates that the magazine can either be removed and/or a new one can be inserted, and that the output door can be removed and an empty one placed.

Input Magazines

Color Code	Information
Red	Magazine is in the 15-minute warm up period.
Pink	Magazine warm up period is complete. System is ready to embed.
Dark blue bars with dark border	Magazine emptied. The number of cassettes processed displays below the graphic.
Dark blue bars, dark border	Cassettes are being taken out of the magazine. The number of cassettes displayed is incremented each time a cassette is taken from the magazine.
Gray, with light border, no bars	No magazine is detected.

Base Molds and Output Doors

Color Code	Information
Green	Standard Cassettes
Orange	26 x 19mm Biopsy Cassettes
Maroon	Specialty cassettes (Orientation, Core, Shaved)
Gold	13 x 13mm Biopsy Cassettes
Blue	Undefined (treated as a standard)
Door has blue background, colored bars, dark border	Output door ready to be removed. The number of blocks is shown below the graphic.
Door has gray background, colored bars, light border	The output door is being filled with blocks. The number of blocks shown is incremented each time one block is added.
Door has gray background and light border	Output door is empty waiting to receive blocks.
Door has gray background with dark red border	Output door is not present.

For example, in Figure 4-K, output doors 1 and 4 are empty and ready to accept cassettes, output door 2 is full and ready to be removed, while door 3 is being filled with cassettes. The colored bars show the types of cassettes present.

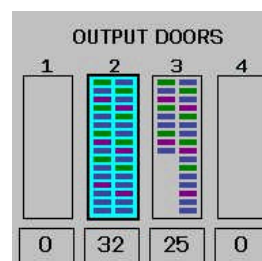


Figure 4-K: Output Door Color Codes

OPERATION

Embedding Cassettes

Once loaded with magazines, the AutoTEC will start automatically and embedding will begin after the system checks and 15-minute magazine warm up period are complete. During system operation it is possible to continually replace empty magazines with loaded magazines and full output doors with empty ones.

The Run screen shows the progress of the embedding process for each cassette in the run. An example is shown below.

NOTE: Cassettes are transferred to the output doors in the exact sequence they are taken out from the input magazines. For example, if input magazine #1 contained 14 cassettes, these cassettes will be embedded and 14 blocks will be placed in output door #1. If the next ready magazine is in position #4 and contains 5 cassettes, the 5 completed blocks will be found in output door number #4.

An empty slot will be left in the output door, when a cassette or an embedded block is dropped to the chute.

The Embedding Run screen in Figure 4-L shows that magazine #1 was loaded at full capacity and that all 32 cassettes have been removed, embedded, and transferred to output door #1. 8 cassettes have been pulled out from input door #2, 1 embedded block is already inserted to the output door #2 and 6 cassettes are on the base molds. Base mold #7 is disabled for some reason. Input magazine #3 (in pink) has completed 15 minutes warm up time and is waiting to be processed next. There is no cassette in Input #4 magazine. A total of 14 specialty, 12 biopsy, 7 standard cassettes, and 8-13x13 biopsy have been embedded so far.

The TOTALS are incremented every time a cassette is placed in a base mold. They are sorted by cassette type. The TOTALS are reset whenever a new user logs in, the system shuts down, or the count exceeds 9,999. These counts are recorded in the statistics.

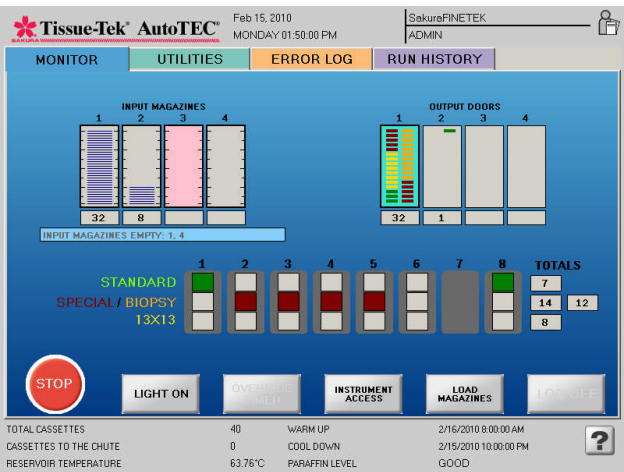


Figure 4-L: Run screen, Magazines Heated

NOTE: The input door sensor system is able to detect the presence of magazines and if they contain cassettes or are empty. However, it cannot tell in advance how many cassettes are present in a given magazine when first loaded. The system counts cassettes as they are removed from each magazine and displays that total below the input magazine graphic.

End of Run and Removing Output Doors

By definition, a run consists of all cassettes in a magazine. Once the cassettes initially loaded into a magazine are all embedded and transferred to an output door, an audible alarm sounds and a prompt will appear in the message area at the bottom of the screen indicating that the run is complete for that magazine. Within 1-2 seconds the completed output door will be highlighted. When the output doors have been removed, the display will update the status of the output door within 1-3 seconds. If no cassettes are being embedded, and as the last door is removed, it then takes 30 seconds to update the door status. When the door is removed the count beneath is also reset simultaneously and the message at the bottom of the screen now only reflects the current status. If all output doors are removed, there will be no old message left to clear the output door. Remove all specimen blocks, from the output door or use the output door as transport tray.

To remove one or more doors:

1. Push the small red button **1** located above the upper-right corner of the output door to release the latch (Figure 4-M).
2. Grip the door handle and firmly pull the door away from instrument.
3. To replace, place the bottom edge of the empty door in the channel and push the door towards the instrument until it latches with a distinct click. The click is required for the instrument to recognize the door is in place.

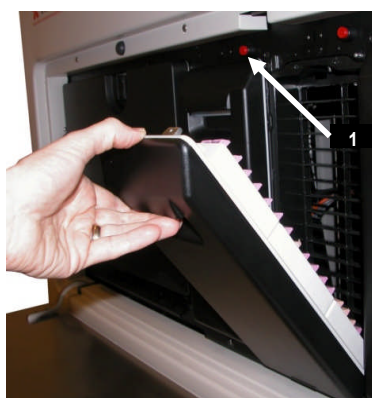


Figure 4-M: Removing an Output Door

Add Paraffin

If the paraffin level falls below a certain point, an on-screen message and audible alarm will prompt the user to add paraffin to the reservoir. At this point, the system has sufficient paraffin to embed at least 128 more cassettes, or four full magazines.

NOTE: While the system is running, only molten paraffin should be added; while it is in its warming cycle, pellets may be added to the reservoir.

NOTE: Use only Tissue-Tek Paraform Processing/Embedding Medium, Formula 3 (product code #7052).

NOTE: When the paraffin reservoir temperature drops below an acceptable range the instrument will restart after the user acknowledges the displayed message.

Cassette Recovery Chute

In certain instances, an improperly assembled Paraform frame and cassette will be placed in the cassette recovery chute. The chute is located behind a spring-loaded hinged door on the left side panel. The system will continue to process cassettes, and prompt the operator to remove the Paraform Cassette from the chute. Touch ☒ to confirm that the cassette has been removed.

The gripper is programmed to attempt to pick a framed cassette from a magazine in three attempts. The gripper may miss the cassette on the first attempt but move to the chute and then return for another attempt which is successful. If the cassette type check sensor validation fails for the paraform cassette coming from the magazine in the input door, the gripper will place that cassette in the chute and return to the input door to grab the next cassette. "CASSETTES SENT TO CHUTE" count on screen will be incremented each time the chute sensors detects cassette/frame dropping to the chute (Figure 4-N).

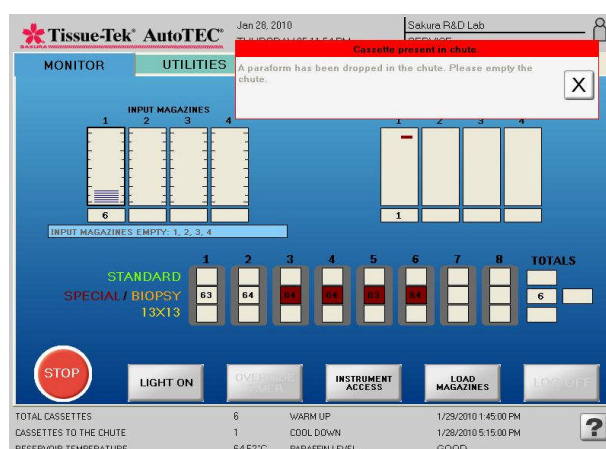


Figure 4-N: Cassette Recovery Message

OPERATION

CARE OF THE INSTRUMENT

Introduction

This section provides information on how to care for and maintain the Tissue-Tek® AutoTEC® to keep it in good condition and to ensure proper operation.

Proper maintenance of the AutoTEC is essential to maintain the system in operative condition. This section provides information on:

- Routine Maintenance
- Magazine Maintenance and Cleaning

Routine Maintenance

Routine maintenance procedures include:

- Exterior maintenance
- Paraffin Trough cleaning
- Output grid sensor cover glass cleaning
- Paraffin Reservoir and filter
- Magazines
- Output doors
- Splash guards
- Touch screen
- Gripper Cleaning

Perform these routine maintenance procedures at the following frequencies:

Maintenance Activity	Frequency
Exterior maintenance	Weekly or more often if necessary.
Paraffin Trough cleaning/replacing	After every eight hours of operation, or as needed.
Output grid sensor cover glass cleaning	Daily or more frequently if necessary.
Paraffin Reservoir and Filter Cleaning	Every two weeks, or more frequently if paraffin in the reservoir appears dirty.
Magazine cleaning	After every use.
Output Door inspection and cleaning	Inspection after every use. Cleaning every month.
Splash guards cleaning	After 10,000 cassettes.
Touch screen & optional keyboard and Mouse	Monthly.
Gripper	Weekly or more often if necessary.

Exterior Maintenance

Keep the exterior of the Tissue-Tek AutoTEC cabinet free of dust and clutter. Typically, wiping the cabinet with a clean wet cloth will keep the instrument cabinet dust free. Do not use solvents of any kind on the cabinet or control panel; in particular, do not use acetone on the Sakura logo or any other labeled or printed surface.

Use hospital-grade disinfectants to disinfect exterior surfaces. Use surface cleaners such as Windex™ or Formula 409™ to clean the Control Panel touch screen.

Paraffin Trough Cleaning/Replacement

The paraffin trough is designed to catch paraffin drips from the magazines as they are heated (Figure 5-A). It is located beneath the input door. Paraffin drips should be cleaned from the trough after eight hours of operation. Pull the trough out by grasping both ends and pulling it out. Clean the trough or discard it and replace with a new paraffin trough.



Figure 5-A: Paraffin Trough

Input Doors

Paraffin may accumulate at the top of the input doors. Use a clean soft cloth or Kimwipes® to remove the buildup. This should be done at least once a day.

CARE OF THE INSTRUMENT

Output Grid Sensor Cover Glass Cleaning

The output grid sensor is located along the lower channel of the output doors and is protected by a cover glass (See Figure 5-B). Small particles of paraffin **Cover Glass** on the cover glass and must be cleaned daily or more frequently if necessary. To clean the cover glass, wipe away the paraffin debris with a soft cloth, soft brush, or Kimwipes®.

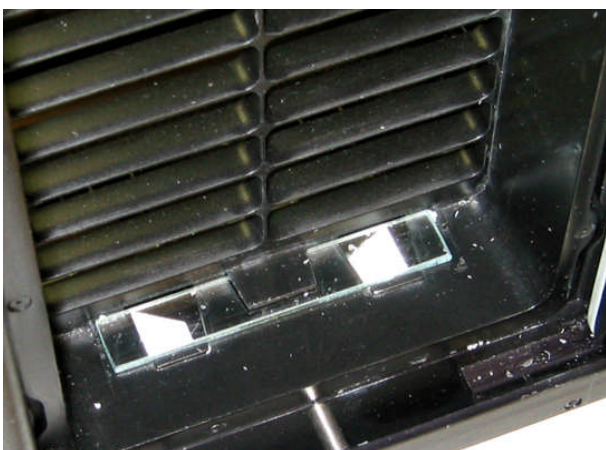


Figure 5-B: Output Grid Sensor Cover Glass

Paraffin Reservoir and Filter Cleaning

It is recommended that the reservoir be cleaned every two weeks or more frequently depending on the accumulation of dirt visible in the paraffin.

Clean the reservoir with a pair of 12 inch forceps and pieces of gauze sponge as follows:

1. Place the gauze sponges into the paraffin in the reservoir.
2. With the forceps, move the gauze slowly around, capturing as much of the dirt particles as possible.
3. Gently lift the gauze sponges out and discard them.

Alternatively, once a month allow the reservoir to run low toward the end of the day. As the paraffin starts to cool and solidify during the cool down period, but while it is still pliable, use a plastic scraper to remove it from the reservoir. Add paraffin pellets to the reservoir to prepare for the next warming cycle.

Filter Cleaning

CAUTION: When using solvents, refer to their Material Safety Data Sheets and always observe precautions specified there.

Clean the filter as follows:

NOTE: Clean the filter only **after** cleaning the reservoir, as described above.

NOTE: Clean the filter one at a time to prevent contaminants from getting into the paraffin dispense tube.

1. Access the filter by removing the panel cover that covers it.
2. Use the tool provided to loosen the two set-screws that hold down the tabs of the filter assembly. One turn counterclockwise should be enough (Figure 5-C).

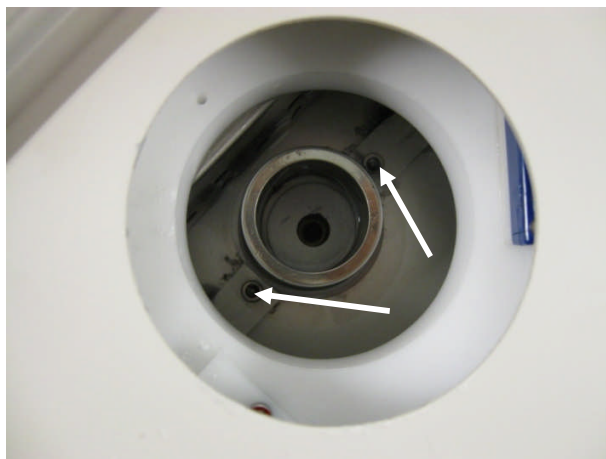


Figure 5-C

Section 5

3. Turn the filter 90° so it can be lifted out of the reservoir. Rotate by holding the top of the filter until tabs are turned away from the locked down positions (Figure 5-D).

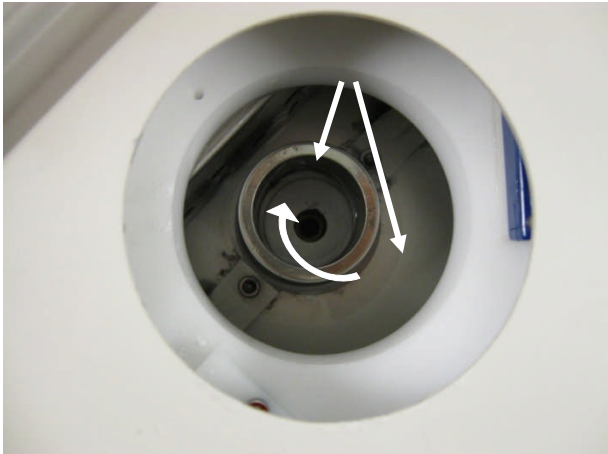


Figure 5-D

4. Lift the filter out for cleaning (Figure 5-E).



Figure 5-E

5. Use a bath of solvent to clean wax and debris out of the filter.
6. Dry the filter and reinstall it in the reservoir, taking care to tighten the screws down on the tabs of the filter.

7. Gently pull the parasitic filter straight out from the center (Figure 5-F).

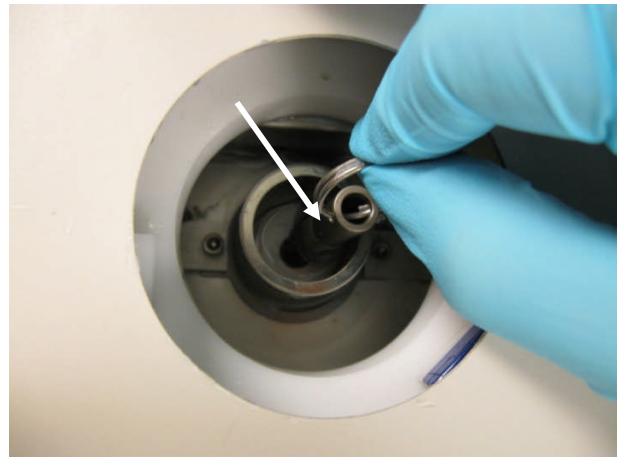


Figure 5-F

8. Use a bath of solvent to clean the wax filter.
9. Dry the filter and reinstall it in the reservoir (Figure 5-G).



Figure 5-G

10. Place the panel cover back.

CARE OF THE INSTRUMENT

Magazine Cleaning

Magazines must be free of excess paraffin before they are loaded with cassettes. A dishwasher using a heated cycle can be used or alternatively the cleaning cycle of an overnight processor such as the Tissue-Tek® VIP®.

Output Door Inspections and Cleaning

Output doors must be periodically inspected for deformed spring clips (Figure 5-H). Do not use a door with any deformed springs; contact Sakura to have it replaced.

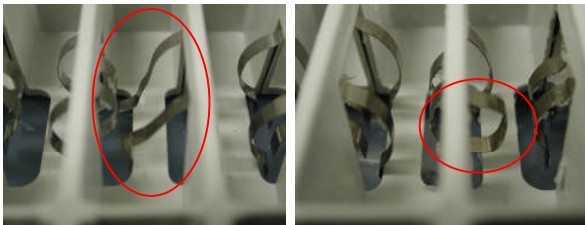


Figure 5-H: Examples of deformed Output Door springs

Splash Guard Cleaning

Use the scraper to clean accumulated paraffin on splash guard (Figure 5-J) during the cool down period when the Cleaning Request message (Figure 5-I) appears or depending on the accumulation of paraffin which could prevent efficient gripper/stager traveling.

CAUTION: When cleaning splash guard be careful not to bend any base mold posts.

NOTE: The default setting for the maximum number of cassettes is 10,000.

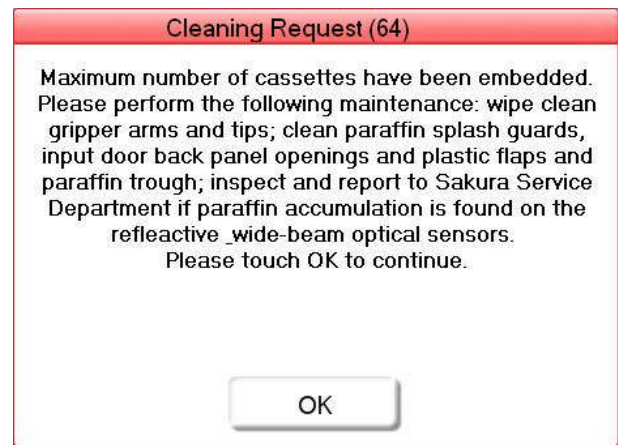


Figure 5-I

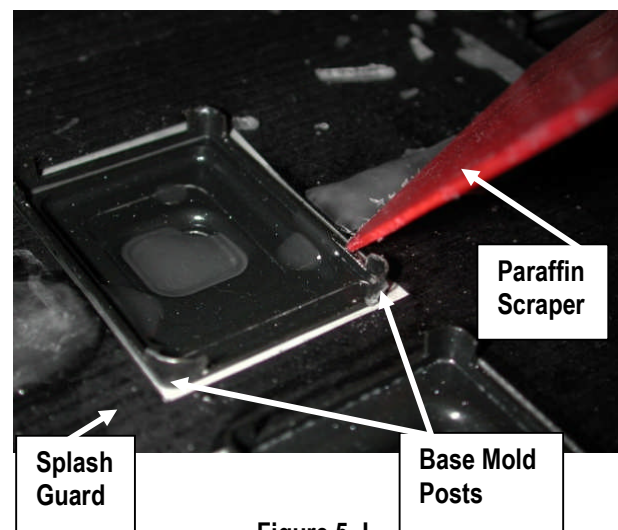


Figure 5-J

Optional: Touch Screen, External Keyboard, and Mouse Cleaning

Touch screen, keyboards, and other peripherals must be free of excess paraffin to ensure consistent operation. Remove excess paraffin by using the scraper and use surface cleaners such as Windex™ or Formula 409™. Use of dust covers is recommended.

Gripper Weekly Maintenance

The gripper arms should be cleaned weekly. To prevent paraffin accumulation, two possibilities are recommended.

1. **First run on Mondays** – Each Monday after the operator loads magazines and closes the input door, on the first cycle of the day, the following message will be displayed (Figure 5-K):

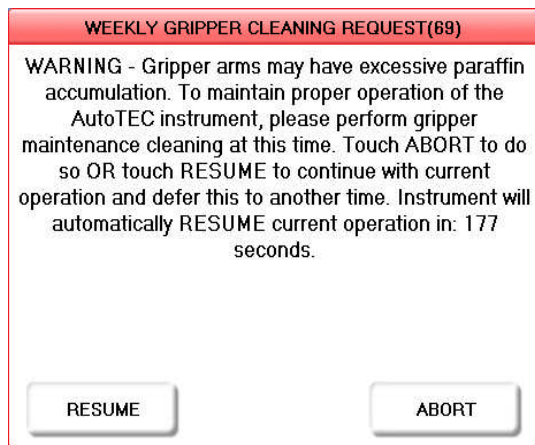


Figure 5-K

To clean the gripper arms select ABORT on the above message box. If the time is exceeded, the system will resume current operation in 180 seconds. To override cleaning at this time select RESUME to let the instrument continue with the current task. If operator selects ABORT to clean the gripper arms, then the stager will move over standard base mold #1 and gripper will move above base mold #5 giving enough clearance to clean the bottom of the gripper arms. Once in the position, wait for the following message to be displayed on the screen before attempting to open the door (Figure 5-L).

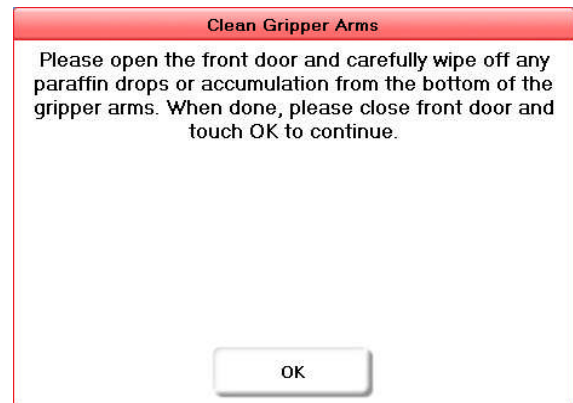


Figure 5-L

Open the front door to clean the gripper arms (Figure 5-M) and follow Gripper Arms Cleaning Procedure.

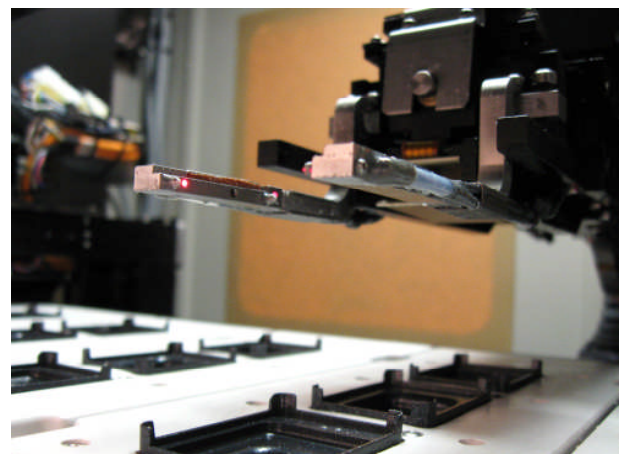


Figure 5-M

CARE OF THE INSTRUMENT

Gripper Arms Cleaning Procedure

The instrument will prompt the operator to clean the gripper arms once a week (Figure 5-N).

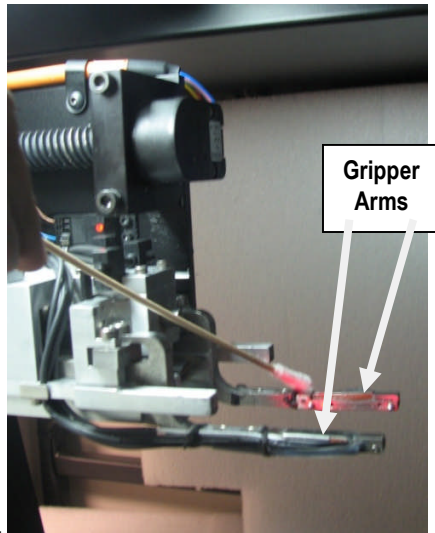


Figure 5-N

Cleaning the gripper arms should be performed during the cool down period. Use dry foam swabs (Product code #8050) or dry lint-free cloths such as Kimwipes® to remove the accumulated paraffin on gripper arms as shown in Figures 5-O & 5-P.

CAUTION: Do not use cotton Q-tips or cotton cloth to clean the gripper arms. Lint left from cleaning may interfere with the sensors.

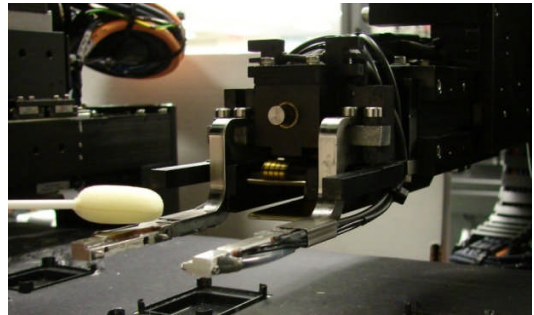


Figure 5-O

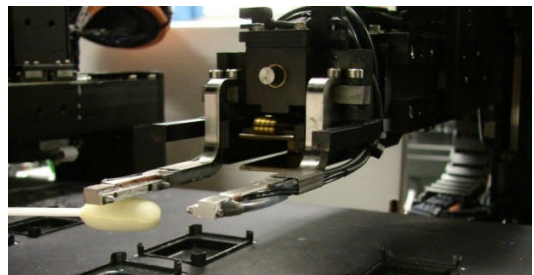


Figure 5-P

After cleaning the gripper, close the front door to allow the instrument to resume operation. After closing the front door acknowledge message box on screen to continue with the cycle (Figure 5-L).

NOTE: Do not load magazines when 4 hours warm up timer is on screen. Before loading the magazines please make sure the timer is NOT on screen (either override the timer or wait 4 hours for the timer to go off). The paraffin inside the delivery tubes may still be solidified and the instrument will not be ready for robotic system movement.

2. **Gripper Arms Parallel Check fails:** If Gripper Parallel Check fails, the instrument prompts the operator to clean the gripper arms (Figure 5-Q).

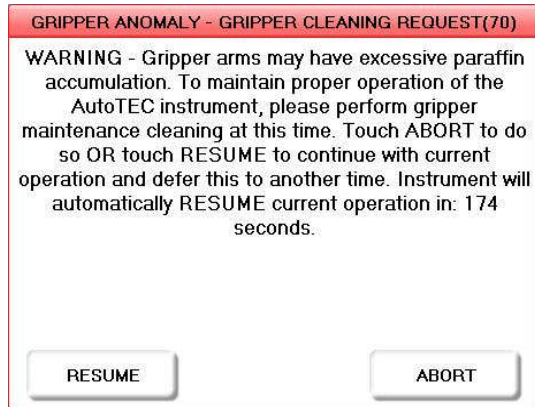


Figure 5-Q

To clean the gripper arms select ABORT on the above message box. If the time is exceeded, the system will resume current operation in 180 seconds. To override cleaning at this time select RESUME to let the instrument continue with the current task. If operator selects ABORT to clean the gripper arms, then the stager will move over standard base mold #1 and gripper will move above base mold #5 giving enough clearance to clean the bottom of the gripper arms. Once in the position, wait for the following message to be displayed on the screen before attempting to open the door (Figure 5-R).

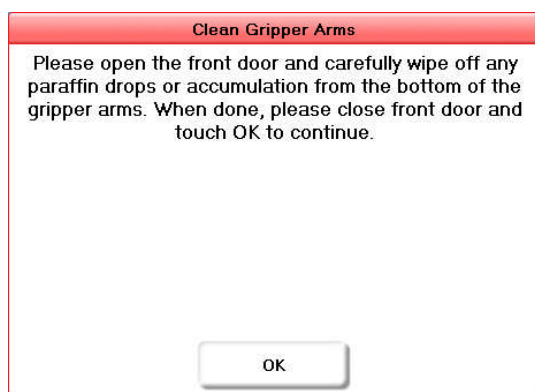


Figure 5-R

Open the front door to clean the gripper arms (Figure 5-S) and follow Gripper Arms Cleaning Procedure located on the previous page.

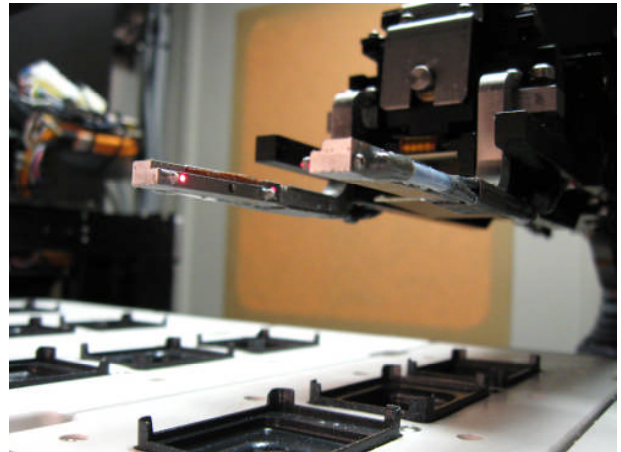


Figure 5-S

After cleaning the gripper, close the front door to allow the instrument to resume operation. After closing the front door acknowledge message box on screen to continue with the cycle (Figure 5-R).

NOTE: During an embedding cycle, if “Gripper Parallel Check Failure” occurs there will be NO request to clean the gripper arms since they were successfully checked (and passed) before starting the cycle.

CARE OF THE INSTRUMENT

TROUBLESHOOTING

Error Recovery

Selected components and system parameters are monitored when the Tissue-Tek® AutoTEC® is turned on and while it is operating, to ensure that the instrument is functioning properly. If a monitored component or parameter falls outside established limits of operating criteria, not only does an error message display in a pop-up window on the control panel but also an audible alarm sounds.

Error messages are shown in the table below. They include:

- Error codes
- Titles (descriptions of errors)
- Messages with instructions on the steps to take for error recovery
- Actions required to recover from the error
- Document error codes for reference when contacting Sakura Finetek for service

NOTE: Internal events are recorded in the Error Log but are not considered errors which require corrective action. An example of such an event is the second or third attempt of the gripper to pick up a framed cassette.

TROUBLESHOOTING

ERROR CODES AND MESSAGES

Error Codes and Messages				
Error Code	Title		Message	Result, or Action Required
	Error Type	Error Name		
1	UNEXPECTED FRAME PROBLEM		Unexpected Frame Problem	Error Log
2	AXIS STALL	AXIS STALL IN THE U AXIS	User can interrupt the stall recovery process by touching ABORT button; this allows user to access the instrument and move any axis manually, if required. User can touch RESUME button to immediately start stall recovery process. This is a timed message box, which is displayed for 180 seconds only, after <u>180 seconds</u> and no response from the user it will automatically start stall recovery process and will then resume the current operation. This message is displayed for each axis stall telling the axis name (X/Y/Z etc.) and error number; there are different error numbers for different axis.	Touch ABORT or RESUME
3		AXIS STALL IN THE INPUT DOOR		
5	BLOCK/CASSETTE TO CHUTE	BLOCK/CASSETTE DROPPED TO CHUTE	1) Cassette dropped to chute while grabbing cassette from input door. 2) Cassette dropped to chute while checking frame. 3) Cassette dropped to chute while checking type of cassette. 4) Cassette dropped to chute while doing front frame check. 5) Block/Cassette dropped to chute during Error Recovery. 6) Block dropped to chute while picking from base mold #<1-8>.	Chute message displayed
6	GRIPPER FAILURE	GRIPPER FAILED TO OPEN AT BASE MOLD	The gripper failed to open at the base mold. Open the front door and reset the Paraform Cassette into base mold #<1-8>. Check the gripper and base mold for excess paraffin and obstructions. Once the Paraform has been seated in the base mold, close and latch the door then touch OK to resume instrument operation.	Touch CONTINUE
7	BLOCK NOT REMOVED FROM BASE MOLD #<1-8>	BLOCK NOT REMOVED FROM BASE MOLD	Touch [ABORT] to open the front door and remove the block from base mold #<1-8>, and remove any excessive paraffin or obstructions on or near the base mold. Touch [RESUME] to disable the base mold and continue with current operation.	Touch ABORT or RESUME. User has 180 seconds to respond to message.
			Touch [ABORT] to open the front door and remove the block from base mold #<1-8> and remove any excess paraffin or obstructions on or near the base mold. When finished, close and latch the front door and touch [CONTINUE] to resume the instrument operation. If it is not possible to remove the block from the base mold, close and latch the front door and touch [CONTINUE]. The system will check the base mold and provide further instructions.	Touch ABORT Touch CONTINUE
8	AXIS STALL	AXIS STALL IN THE U AXIS	User can interrupt the stall recovery process by touching ABORT button; this allows user to access the instrument and move any axis manually, if required. User can touch RESUME button to immediately start stall recovery process. This is a timed message box, which is displayed for 180 seconds only, after <u>180 seconds</u> and no response from the user it will automatically start stall recovery process and will then resume the current operation. This message is displayed for each axis stall telling the axis name (X/Y/Z etc.).	Touch ABORT or RESUME
9		AXIS STALL IN THE W AXIS		
10		AXIS STALL IN THE X AXIS		
11		AXIS STALL IN THE Y AXIS		
12		AXIS STALL IN THE Z AXIS		

Error Codes and Messages				
Error Code	Title		Message	Result, or Action Required
	Error Type	Error Name		
13 15 16 17 19	HEATER TEMPERATURE PROBLEM		The [reservoir / copper tube 1 / copper tube 2 / flex tube / valve/nozzle] has dropped below acceptable operating temperature. Base molds will be cleared and no more cassettes will be embedded. The paraffin system heaters will be turned off, and the instrument MUST be serviced before embedding can continue.	Perform action/s requested.
19	HEATER TEMPERATURE PROBLEM		The frame heater -<temperature> is out of acceptable operating range <Min.-Max.>, instrument will now shut down, empty input door and all output doors. Contact Sakura Service Department.	
14 18 20	HEATER TEMPERATURE PROBLEM		The [secondary reservoir / pusher pins / stager] [is / are] outside acceptable operating temperature. Current magazine will be finished and base molds cleared. The instrument SHOULD be serviced before embedding continues.	Perform action/s requested.
21 22	HEATER TEMPERATURE PROBLEM		Heater [A / B] in input door chamber (#) has dropped below acceptable operating temperature. The system will not use this input chamber until temperature is within normal range. The instrument MUST be serviced before chamber (#) can be used.	Perform action/s requested.
			Heater [A / B] in input door chamber (#) has risen above acceptable operating temperature. Cassettes in the magazine will be embedded and base molds cleared. The instrument SHOULD then be serviced before embedding continues	
23	HEATER THERMAL FUSE PROBLEM		During a check of the system heaters [reservoir / secondary reservoir / copper tube 1 / copper tube 2 / flex tube / valve/nozzle/ drip tray/ ID-(#)A/ ID-(#)B] thermal fuse was discovered to be functioning improperly. The instrument will not run until this problem is fixed. Please contact maintenance for further assistance.	Perform action/s requested.
24 25	HEATER TEMPERATURE PROBLEM		The [tamper / gripper] heater -<temperature> is out of acceptable operating range <Min.-Max.>, base molds will be cleared, no more cassette will be embedded.	Perform action/s requested.
26	HEATER TEMPERATURE PROBLEM		The drip tray heater -<temperature> is out of acceptable operating range <Min.-Max.>, instrument will continue embedding as normal. Contact Sakura Service Department.	Perform action/s requested.
27	REQUEST	OUTPUT DOOR #<1-4> IS NOT PRESENT	Please replace Output Door #<1-4>, then touch OK to resume instrument operation.	Touch OK
		EMPTY AND REPLACE OUTPUT DOOR #1	Operation WILL NOT continue until Output Door #1 is in place and empty. Once the Output Door has been replaced, touch OK to resume instrument operation.	Touch OK
27	REQUEST	EMPTY AND REPLACE OUTPUT DOOR #2	Operation WILL NOT continue until Output Door #2 is in place and empty. Once the Output Door has been replaced, touch OK to resume operation.	Touch OK
		EMPTY AND REPLACE OUTPUT DOOR #3	Operation WILL NOT continue until Output Door #3 is in place and empty. Once the Output Door has been replaced, touch OK to resume operation.	Touch OK
		EMPTY AND REPLACE OUTPUT DOOR #4	Operation WILL NOT continue until Output Door #4 is in place and empty. Once the Output Door has been replaced, touch OK to resume operation.	Touch OK

TROUBLESHOOTING

28	HEATER TEMPERATURE PROBLEM	FRAME HEATER OUT OF RANGE	The Frame Heater temperature [##] is out of acceptable range [Min: ##, Max:##] Please empty all input & output doors and contact Sakura Service Department for further instructions. Please touch RESUME to restart the application or ABORT to shutdown the instrument.	Perform action/s requested
29	HEATER TEMPERATURE PROBLEM	FRAME HEATER RTD IS OPEN	The [GRIPPER FRAME HEATER] RTD is Open. The instrument MUST be serviced before embedding can continue.	Touch OK
33	REQUEST	OUTPUT DOOR #<1-4> IS NOT EMPTY	Please empty Output Door #<1-4>, then touch OK to resume instrument operation.	Touch OK
35	CASSETTE/ BLOCK PROBLEM	DROPPED CASSETTE/BLOCK INSIDE THE INSTRUMENT	A cassette/block might have been dropped inside the instrument. Please open front door and if required, back doors and inspect for any dropped cassette/ block and retrieve it. Close all the doors and please touch OK when done.	Touch OK
36	MISSING CASSETTE		NO CASSETTE DETECTED IN FRAME	Chute message displayed
37 38	MISSING CASSETTE		NO FRAME DETECTED IN GRIPPER	Chute message displayed
39	FRAME POSITION PROBLEM	PARAFORM CASSETTE INCORRECTLY POSITIONED IN BASE MOLD	Open the front door and reset the Paraform Cassette in base mold #<1-8> [cassette type]. Once the cassette has been reset, close and latch the front door then touch OK to resume instrument operation.	Touch OK
41	MISSING BLOCK PROBLEM	BLOCK NOT REMOVED FROM BASE MOLD	Open the front door and, if necessary, the rear doors and retrieve the missing block from base mold #<1-8>. Remove any excess paraffin or obstruction around the base mold. Once the block has been retrieved, close and latch all doors, then touch OK to resume instrument operation.	Touch OK
42	MISSING BLOCK PROBLEM	MISSING BLOCK FROM BASE MOLD		Touch OK
45	U/V STEPPER BOARD PROBLEM	U/V STEPPER BOARD NOT RESPONDING	U/V Stepper Board is not responding. System is trying to recover the error to resume current operation	Error Log
46	W/X STEPPER BOARD PROBLEM	W/X STEPPER BOARD NOT RESPONDING	W/X Stepper Board is not responding. System is trying to recover the error to resume current operation	Error Log
47	Y/Z STEPPER BOARD PROBLEM	Y/Z STEPPER BOARD NOT RESPONDING	Y/Z Stepper Board is not responding. System is trying to recover the error to resume current operation	Error Log
48	SOLENOID DRIVER BOARD PROBLEM	SOLENOID DRIVER BOARD NOT RESPONDING	The Solenoid Driver Board is not responding. Please contact Sakura Service department for further instructions. Please remove all input magazines and empty all output doors then touch OK to shut down the system.	Instrument shuts down if [OK] is touched
49	HEATER CONTROLLER BOARD PROBLEM	HEATER CONTROLLER BOARD NOT RESPONDING	The Heater Controller Board is not responding. Please contact Sakura Service department for further instructions. Please remove all input magazines and empty all output doors then touch OK to shut down the system.	Instrument shuts down if [OK] is touched
50	TEC BOARD PROBLEM	TEC BOARD NOT RESPONDING	The TEC Board is not responding. Please contact Sakura Service department for further instructions. Please remove all input magazines and empty all output doors then touch OK to shut down the system.	Instrument shuts down if [OK] is touched
51	INPUT DOOR PROBLEM	INPUT DOOR BOARD NOT RESPONDING	Input Door Stepper Board is not responding. System is trying to recover the error to resume current operation	Error Log

Section 6

52	FRAME HEATER MOTOR PROBLEM	BOTH THE LIMIT SWITCHES OF FRAME HEATER MOTOR ARE TRIGGERED	Unable to move Frame Heater. Both the limit switches are triggered. Please empty all input & output doors and contact Sakura Service Department for further instructions. Please touch OK to shut down the instrument.	Instrument shuts down if [OK] is touched
53	I/O BOARD PROBLEM	I/O BOARD NOT RESPONDING	The I/O Board is not responding. Please contact Sakura Service department for further instructions. Please remove all input magazines and empty all output doors then touch OK to shut down the system.	Instrument shuts down if [OK] is touched
54	BASEMOLD PROBLEM	TEC DISABLED	Base mold #<1-8> has been disabled due to <High-Low><Heating-Cooling><Temperature> on <Cassette Type>	Error Log
55	BASEMOLD PROBLEM	THERE HAVE BEEN THREE CONSECUTIVE V AXIS STALLS ON A PARTICULAR BASE MOLD	Initiate the process to disable the particular base mold. Abort the process by touching on ABORT or expedite the current process by touching on RESUME. A timed message box appears for the user to act upon, after 180 seconds and no response from the user, it will disable the particular base mold and continue working with the next cassette and base mold.	Touch RESUME to disable or touch ABORT to continue current operation without disabling the base mold.
		3 CONSECUTIVE ABORT COMMANDS ON BASE MOLD SELECTED	The user selected three consecutive ABORT commands on base mold #<1-8>. System will now disable base mold #<1-8>	Touch OK
		BLOCK NOT REMOVED FROM BASE MOLD	Base mold #<1-8> disabled due to block not removed.	Error Log
56	NON-RECOVERABLE ERROR	INSTRUMENT EXPERIENCES 3 CONSECUTIVE STALLS WITHIN 20 MINUTES	The instrument has experienced a non-recoverable error with the [U/V][W/X][Y/Z] [Input Door] Stepper. Please remove all input magazines and empty all output doors, instrument will now shut down. Contact Sakura Service Department for further instructions.	Contact Sakura Service Department
57	MAGAZINE PROBLEM	MAGAZINE NOT SEATED	Input Magazine(s) #n not seated properly. Please reseal these magazines. Touch OK to open input door now.	Touch OK
58	MAGAZINE PROBLEM	UNABLE TO HOLD CASSETTE FROM INPUT DOOR	Check magazine (#) for cassettes. NOTE: Removing magazine will cause the magazine to warm up for 15 minutes. Do not remove any other magazines.	Touch ABORT to open input door and check magazine (#). Touch RESUME to continue with the current cycle. User has 60 seconds to respond to message.
59	SENSOR MALFUNCTION	SENSOR CHECK	The following sensors are not function properly: Failed sensor check. Please contact Sakura Service Department for further instructions.	Touch OK
61	CASSETTE IMPROPER ASSEMBLY		CASSETTE LID OPENED IN FRAME	
62	CASSETTE IMPROPER ASSEMBLY		CASSETTE TABS PUSHED DOWN IN FRAME AT CASSETTE TYPE CHECK	Chute message displayed
63	RUN ABORTED WARNING	OPEN LID DETECTED	Please open the front door and close cassette lid on base mold #X Standard Then touch RESUME to continue current process OR touch ABORT if more time is needed. To prevent base molds and cassettes from being damaged, instrument will continue embedding and clear all base molds (except base mold #X) and stop embedding in 180 seconds.	Touch ABORT or RESUME
64	MAINTAINENCE	CLEAN SPLASH GUARD, GRIPPER & ID PANEL	Maximum number of cassettes-to-embed exceeded (1000), must clean splash guard, gripper, BM covers, ID back openings.	Touch OK

TROUBLESHOOTING

65	RUN ABORTED	RUN ABORTED DUE TO UNPARALLEL GRIPPER ARMS	Run aborted due to unparallel gripper arms (bending upwards/failed to block sensor/bending downwards).	Touch OK
98	POWER – ON PROBLEM	COULD NOT POWER ON THE INSTRUMENT	Could not Power On the instrument. Clear all base molds and empty output doors while this message is displayed. PLEASE DO NOT TURN OFF THE MACHINE. Contact Sakura Service Department for further instructions.	Contact Sakura Service Department
100	AMBIENT TEMPERATURE PROBLEM	AMBIENT TEMPERATURE EXCEEDS ACCEPTABLE OPERATING TEMPERATURE	Ambient Temperature exceeds operating requirements. Embedding Stopped, until ambient temperature lowered.	

Error Code Notes

For errors 13 through 22, the error number will vary depending on the subsystem affected.

#<1–n> denotes a range of numbers that may appear in a message, referring to Input Door chambers, Base Molds or Output Doors, depending on the operating status.

Error Recovery Procedure

If an error message that could lead to system shut down displays, the Sakura Finetek Service department will instruct the user to take the following steps to attempt to recover the error:

1. Remove all paraffin blocks from each of the output doors and all magazines from the input doors.
2. Acknowledge instructions by touching **OK** in the error message pop-up.
3. Wait for the “no input” signal to display on the screen, indicating that the software has shut down properly.
4. Use the main power switch located on the lower-right side panel to turn the AutoTEC off.
5. Look for and remove any Paraform Cassettes that may have dropped below the gripper and/or been placed in the recovery chute.
6. Wait for 15 seconds. Use the main power switch located on the lower-right side panel to turn the AutoTEC on. The application software will load automatically.
7. From the Log In screen, use the screen keyboard to enter user name and password.
8. Touch the **LOG IN** button. The initial run screen displays, with the system start timer visible at upper right.
9. The system will home after warming up and move any Paraform cassettes remaining in the base molds to Output Door 1.

After that the T-E-C self test will follow. When it appears at the lower left of the screen, touch the [OVERRIDE TIMER] button to override the system start timer. Embedding will now resume.

If error messages continue to occur after implementing the error recovery procedure, contact Sakura Finetek for further assistance. See Section 7, Service and Replacement Parts for further information about how to contact Sakura Finetek.

Instrument Access

NOTE: Do *not* access the interior of the instrument through its front or rear doors without making an on-screen request to do so. The doors are interlocked, and opening them without request will require a system reboot.

When it is necessary to access the interior of the system through its front or rear doors, the system will show an on-screen prompt like the one in Figure 6-A. The system will stop embedding; when a door is opened, power turns off, disabling the robot and stopping the base mold fans.

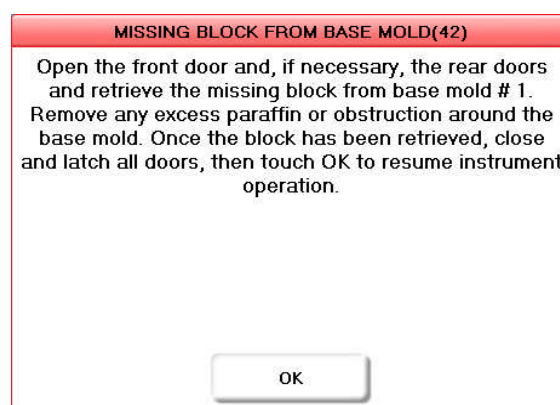


Figure 6-A: Prompt Requiring Instrument Access

Touching INSTRUMENT ACCESS will have the same effect, except that a pop-up dialog will appear (Figure 6-B):

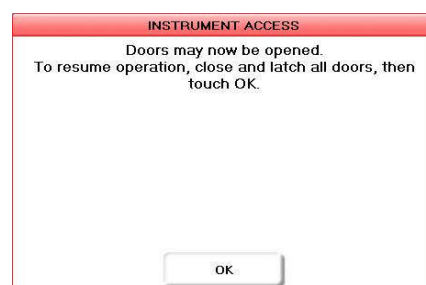


Figure 6-B: Instrument Access Request Acknowledged

TROUBLESHOOTING

For rear access, use a 5/32" (4mm) Allen wrench to turn the two latches, and swing the doors open. (This tool is included in the AutoTEC accessory kit).

To access the base molds from the front, use the Allen wrench to release the two door latches (Figure 6-C).

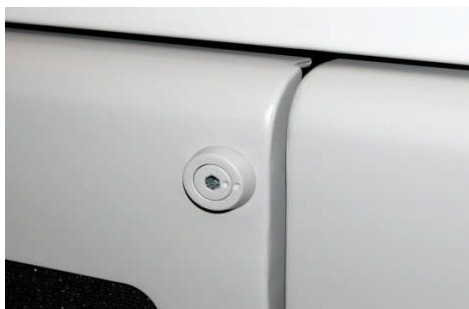


Figure 6-C: Front Door Latch

The door may then be opened (Figure 6-D):



Figure 6-D: Front Door Open

Once access is complete and the doors are closed and latched, touching CONTINUE or OK in the dialog will return the system to normal operation.

If any robotic part was moved while the instrument was open, the system will automatically go to its original configuration and then take up embedding where it left off.

Disabling Base Molds

If the instrument was accessed but a block is still detected in the base mold, the system will prompt the operator to remove the block again. (Figure 6-A) After three unsuccessful attempts to remove the block, the system will disable the base mold in question.

NOTE: Only users with a service-level log in can re-enable a base mold once it is disabled.

Disabling a base mold slows throughput, since blocks must be cooled for the same amount of time regardless of how many base molds are in operation. Disabled base molds should be replaced and serviced as soon as possible.

Disabled Base Molds

A disabled base mold appears on-screen without contents, as seen in figure 6-E.



Figure 6-E: On-Screen Display of Disabled Base Mold

Disabling More Than Three Base Molds

NOTE: The occurrence of this situation is very unlikely.

The instrument **will still run** with four or up to seven base molds disabled; if three base molds are disabled and the operator attempts to disable a fourth, a message will appear (Figure 6-F) to warn the operator that the system throughput will slow down. Do not attempt to load more magazines.

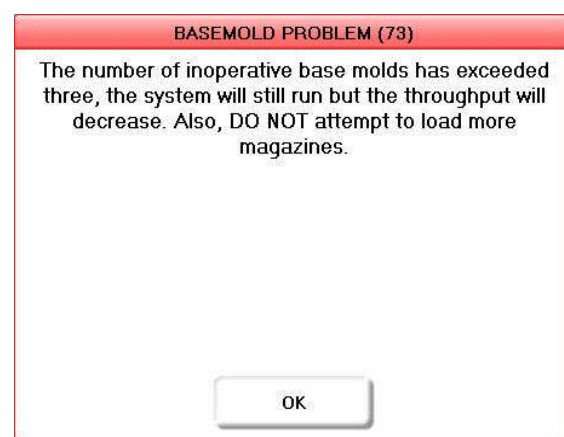


Figure 6-F

If the operator continues, another message will prompt the operator to remove any block that may be present in the disabled base mold when the cycle is complete (Figure 6-G).



Figure 6-G

If base mold #8 is disabled, then an additional button [MOVE STAGER] will appear on the screen (Figure 6-G).

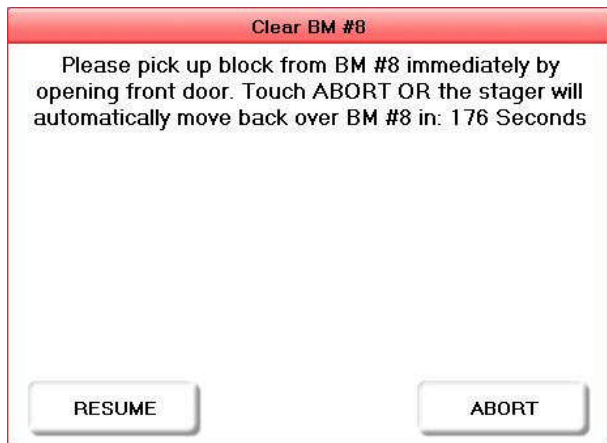


Figure 6-H

Select this button to move the stager so that the operator has access to the block in base mold #8. Once [MOVE STAGER] is selected, the operator will be prompted to remove the block from base mold #8 (Figure 6-H).

Magazine Problem



Figure 6-I: Magazine Problem

A magazine problem will generate the message shown in Figure 6-I. If the problem persists, remove the magazine and reseat the cassettes. If this action does not correct the problem, try a different magazine. If the problem

cannot be resolved, do not use this magazine position and call for service.

Cassette Lid Open

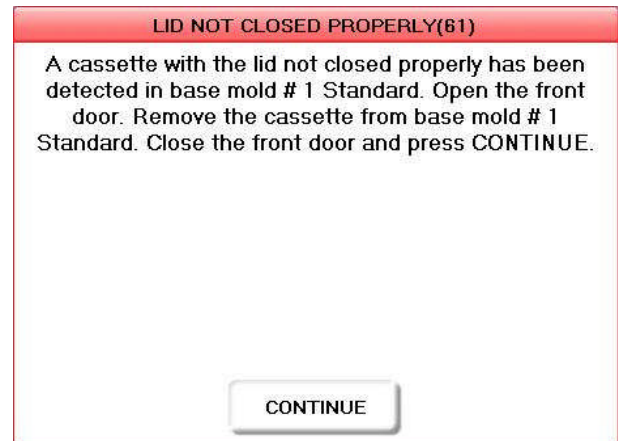


Figure 6-J: Cassette Lid Not Closed

If the instrument detects that a Paraform Cassette lid is open, the gripper will place the cassette on a standard base mold without performing the Cassette Type check and generate the message shown in Figure 6-J. Follow the instructions in the message screen and press CONTINUE then the gripper will retrieve a new cassette from the input door and continue.

TROUBLESHOOTING

SERVICE AND REPLACEMENT PARTS

Service

If a problem occurs with the Tissue-Tek® AutoTEC® that cannot be solved by implementing the recommended corrective actions listed in Section 6, Troubleshooting, and instrument failure is apparent, the Sakura Finetek Technical Support Department is available to assist.

Prior to contacting the Technical Support Department, obtain **model number, installation date, and warranty period** information, which will be required by the Technical Support Representative. Record this information in the blanks below for quick reference.

AutoTEC Model No. _____

AutoTEC Serial No. _____

Installation Date _____

Warranty Period _____

NOTE: To determine the model number of the AutoTEC instrument, check the Serial/Rating label at the lower left corner of the right side panel of the instrument or touch the Software Version icon in the Utilities screen.

Where to Call for Service

If located within the United States, contact the Technical Support Department of Sakura Finetek USA, Inc. by calling toll free:

1-800-725-8723, Menu Option “2”

In countries other than the United States, contact the nearest authorized Sakura Finetek instrument distributor or representative for service information and technical assistance.

Replacement Parts

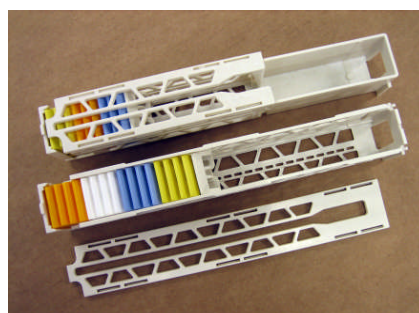
Replacement parts include:

- User replacement accessories
- Consumables

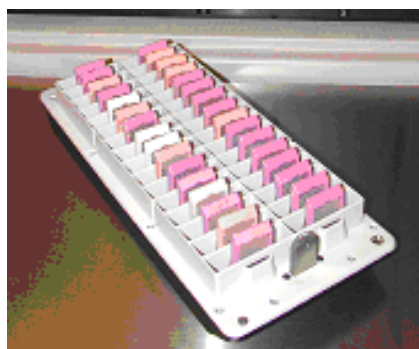
User Replaceable Accessories

Accessories for the Tissue-Tek® AutoTEC® include:

- 32-cassette magazine (product code 7005): includes one cover. Compatible with the Tissue-Tek® VIP® tissue processors. 4/pkg.
- 20-cassette (product code 7006): includes one cover and 1 adapter. Compatible with the Tissue-Tek® Xpress® Rapid Tissue Processor. 4/pkg.



- Handles for Tissue-Tek® Xpress® compatible magazines (product code 7007): 6/pkg
- Paraffin Scraper (product code 1550)
- Output Doors (product code 7008): 2/pkg



- Paraffin Trough (product code 7010)



SERVICE AND REPLACEMENT PARTS

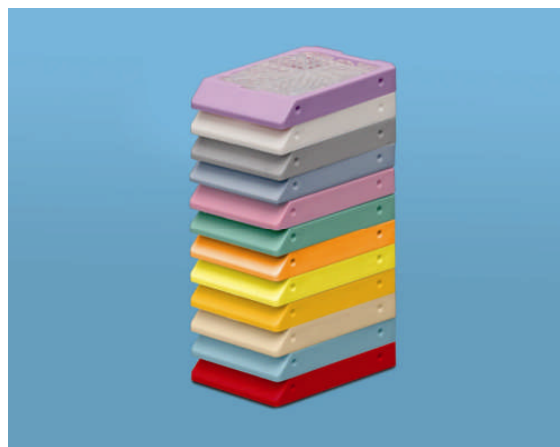
Consumables

- Tissue-Tek® Paraform® Processing/Embedding Medium, Formula 3 (product code 7052): 8x1kg
- Tissue-Tek® Paraffin Trough (product code 7011) 12 paper troughs/cs
- Tissue-Tek® Paraform® Low Profile Disposable Blades (product code 7089): 10 Dispensers x 50 blades/cs
- Tissue-Tek® Paraform® Sectionable Cassettes: 500/cs
- Tissue-Tek® Cleaning Foam Swabs 25/cs (product code 8050)

<u>Cassette Type</u>	<u>Product Code</u>
Biopsy, 13 x13mm	7019
Biopsy, 26 x19mm	7020
Standard	7021
Orientation	7022
Shaved Biopsy	7023
Core Biopsy	7024

- Tissue-Tek® Paraform® Frames
Frames are also available stacked for compatibility with the Tissue-Tek® Autowrite™ Cassette printer.

<u>Frame Color</u>	<u>500/case Product Code</u>	<u>Stacked 10x40/cs Product Code</u>
Aqua	7030	7070
Blue	7031	7071
Gray	7032	7072
Gold	7033	7073
Green	7034	7074
Lilac	7035	7075
Orange	7036	7076
Pink	7037	7077
Red	7038	7078
Tan	7039	7079
White	7040	7080
Yellow	7041	7081



Ancillary Products

Ancillary products for the Tissue-Tek® AutoTEC® include:

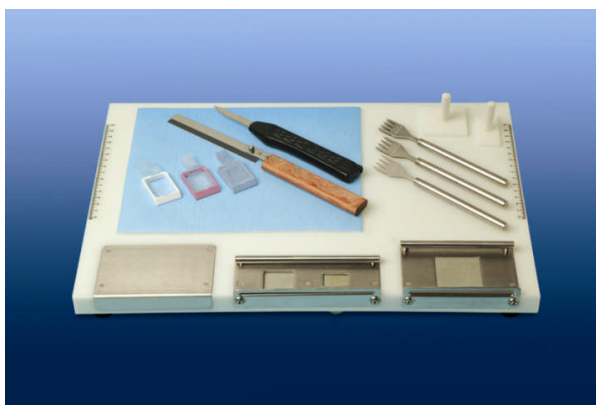
- Tissue-Tek® Accu-Edge® Grossing Board, Standard (product code 4800)



- Tissue-Tek® Accu-Edge® Grossing Board, Large (product code 4801)
- Tissue-Tek® Accu-Edge® Grossing Wells (product code 4802)
- Tissue-Tek® Accu-Edge® Grossing Fork, 1.5 mm (product code 4803)
- Tissue-Tek® Accu-Edge® Grossing Fork, 2.0 mm (product code 4804)
- Tissue-Tek® Accu-Edge® Grossing Fork, 2.5 mm (product code 4807)



- Tissue-Tek® Accu-Edge® Grossing Fork Cleaning Brushes (product code 4814): 10/pkg
- Tissue-Tek® Accu-Edge® Grossing Board Tamper Set (product code 4846)
- Tissue-Tek® Accu-Edge® Grossing Board Gauge Set (product code 4847)
- Tissue-Tek® Accu-Edge® Trimming Handle (product code 4786)
- Tissue-Tek® Accu-Edge® Trimming Blades (product code 4785): 50/pkg
- Tissue-Tek® Accu-Edge® Scalpel Handle (product code 4791)
- Tissue-Tek® Accu-Edge® Scalpel Blades, #62 Pointed (product code 4793): 20/pkg



How to Order Replacement Parts

In the United States, replacement parts can be ordered directly from:

**Order Management
Sakura Finetek U.S.A., Inc.
1750 W. 214th Street
Torrance, CA 90501**

or by calling toll free:

1-800-725-8723

Outside the United States, contact the nearest authorized Sakura Finetek instrument distributor.

SERVICE AND REPLACEMENT PARTS

GLOSSARY

AutoTEC®	A reliable, high-quality automated precision instrument that embeds diagnostic tissue specimens continuously, forming sectionable paraffin blocks.
Base Molds	Molds contained in the base mold assembly that are used to hold, heat, embed, and cool standard, biopsy, or orientation specimens in cassettes.
Cassettes	Paraform components that are sectionable and hold tissue specimens during the embedding process. These cassettes are available in standard, biopsy, orientation, core biopsy, shaved biopsy, and 13 X 13 biopsy versions.
Cool Down	The AutoTEC program mode where the system is not operating and is cooling to room temperature. The paraffin is cooling or in a solid form during this time.
Embedding	The process of surrounding tissue specimens in paraffin blocks.
Embedding Medium	See Paraffin.
Frame	Paraform component into which a cassette is inserted; used by robot to handle cassettes and embedded blocks. Frames are color-coded and have a slanted front surface to write or imprint specimen identification.
Gripper	Solenoid-actuated device mounted on the Y axis that transports each frame/cassette assembly through the system.
Grossing	The process of examining, describing, and trimming tissue specimens to proper size, then loading the specimens into cassettes.
Input Magazines	32-cassette and 20-cassette magazines that hold Paraform cassette assemblies for loading in the AutoTEC.
Magazines	See Input Magazines.
Magazine Warm up Time	15-minute period required to bring Input Magazines to temperature before embedding can begin.
Main Door	When closed, covers input and output doors; when open, provides work-space for magazines and output doors.
Output Doors	Interlocked doors, each equipped with a spring-loaded matrix that firmly holds cassettes in place after processing, yet enables easy access and removal of cassettes. Output doors are removable and can be used as transport trays for embedded cassettes.
Paraffin	The embedding medium used by the AutoTEC. Only Tissue-Tek Paraform Processing/Embedding Medium, Formula 3 (product code 7052) should be used.
Paraffin Trough	A disposable paper trough which is placed directly under the input door to collect the melted paraffin which is present on the magazines and Paraform Cassettes from the tissue processor.
Paraffin Reservoir	A reservoir located on the top right-side panel of the AutoTEC that stores and heats up to 5.38 liters of paraffin, sufficient to embed at least 960 samples.
Recovery Chute	Hinged door on left side panel of the AutoTEC, permitting the retrieval of improperly gripped frames and cassettes. Paraform Cassettes retrieval does not interrupt processing.
Sectionable	A characteristic of a cassette that enables paraffin-blocked tissue to be sectioned using a microtome, ready for placement on slides.

GLOSSARY

Stager Assembly	Positions the paraffin dispensing mechanism over the cassette in the base mold, presses down on the cassette to ensure it is correctly positioned in its frame, and dispenses an even flow of molten paraffin to the correct depth.
Ready Mode	Condition in which the system is warmed up, but is not embedding.
System Warm Up	The AutoTEC program mode during the four-hour period of time required to melt the paraffin in the paraffin reservoir and to bring the instrument to operating temperature.
Tissue-Tek® AutoTEC®	See AutoTEC.
Tissue-Tek® Xpress®	An instrument used to prepare tissue specimens for embedding. The Xpress uses low-power microwave energy to reduce processing time to one hour.
Tissue-Tek® Paraform®	Proprietary name for the sectionable embedding system, including frames and cassettes used in the AutoTEC.

INDEX

A	
Access Levels	3.6
Accessories	7.1
Accessories kit	2.1
Ancillary products.....	7.2
AutoTEC	
Description	1.1
Moving	2.2
Specifications	1.6
B	
Base Molds	
Color coding	4.5
Disabling	6.8
Buttons	
Clean Gripper Arms	3.10
Help	3.2
Instrument Access	3.2
Light On	3.2
Load Magazine	3.2
Log On/Log Off	3.2
Override Timer	3.2
Stop	3.2
C	
Clean Gripper Arms	3.10
Components	
Base mold assemblies	1.4
Cassette sensor array	1.4
Control panel	1.6
Gripper assembly	1.4
Input door assembly	1.3
Instrument access.....	6.7
Magazines and retainers	4.3
Output doors	1.5
Output grid sensor	5.2
Overview	1.1
Paraffin reservoir	1.5
Paraffin reservoir filter	5.2
Paraform recovery chute	1.4
Power switch	2.2
Robotic system	1.3
Stager assembly	1.4
Configuration System Settings	3.7
Consumables	7.2
Contact information.....	2.1, 7.1
E	
Embedding Tracking	
Color codes	4.5
Run screen	4.5
Environmental Factors.....	2.1
Error Log.....	3.15
Error recovery	

Error code notes	6.4
Error codes and messages	6.7
Procedure	6.7
Exporting Data	3.14

G H I

Glossary.....	A.1
Humidity Conditions	1.6
Initial start-up	4.1
Input door	1.3
Installation Procedures	2.1
Instrument Access	6.7
Instrument components	1.2

M

Magazines	
Color coding	4.5
Identifier	4.6
Loading	4.3
Retainer	4.3
Types	4.3
Main power switch	2.2
Maintenance	
Exterior	5.1
Gripper Arm Cleaning	5.6
Magazine cleaning	5.4
Output grid sensor cover glass cleaning.....	5.2
Paraffin Trough Cleaning/Replacement.....	5.1
Reservoir	5.2
Reservoir filter cleaning	5.2
Missing or Damaged Items	2.1

O

On-screen color codes	
Base molds.....	4.5
Embedding tracking.....	4.6
Magazines	4.5
Output doors	4.5
Operation	
Add paraffin	4.7
End a run	4.6
Load magazines.....	4.3
Log in	4.1
Operating sequence	4.1
Preliminary checks.....	4.2
Shut down	3.3
Warm up	3.3, 4.2
Operator interface	1.6

INDEX

P

Paraffin, adding	4.7
Paraform recovery chute	1.4
Passwords, managing	3.6, 3.14
Programming Screens	
Audible alarm setup	3.12
Date and Time Setup	3.13
Days Off Selection	3.8
Enter passwords	3.14
Institution Setup	3.13
Language setup	3.11
Ready/Cool Down Times	3.8
Run History	3.4
System Setup	3.11
User Accounts	3.14

R

Recovery Chute	1.4
Regulatory information	1.7
Replacement parts, how to order	7.3
Robotic system	1.3
Run history	3.4, 3.16
Run Screen Layout	4.5

S

Safety Information	1.1, 1.7
Screens	
Cool Down	3.8, 3.9
Embedding in progress	4.6
Error Log	3.4
Initial Run	4.2
Initial Start Up	4.1
Log In	3.1
Map of interface	3.5
Monitor	3.1
Password entry	3.14, 4.1
Reservoir Temperature	4.2
Run History	3.4
Run screens	4.2, 4.5
Service	3.4
Shut Down	3.9
Software Version	3.10
System Setup	3.11
Utilities	3.3
Warming Cassettes	4.4
Service	7.1
Software	3.3

T

Technical support	7.1
Temperature conditions	1.6
Touch Screen control panel	1.6

U X

Unpacking and Handling	2.1
User icons	
Administrator	3.6
Operator	3.6

